

IMPROVED TOPSHEET FOR CONTACTING HYDROUS BODY TISSUES
AND ABSORBENT DEVICE WITH SUCH A TOPSHEET

5

CHRISTOPHER BEWICK-SONNTAG

TANA KIRKBRIDE

THOMAS W. OSBORN, III

10

NICHOLAS AHR

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation in part of U.S. patent application Ser. No. 09/637,440, filed on August 11, 2000.

15

FIELD OF THE INVENTION

This invention relates to an improved body-contacting surface or topsheet for absorbent articles, bandages, or other such devices, and more particularly to a topsheet that is comfortable when it is placed in contact with hydrous body tissues. The present invention also relates to absorbent devices such as sanitary napkins, tampons, pantliners, interlabial devices, incontinence devices, and bandages, which have such a topsheet. An improved absorbent structure for an absorbent article is also disclosed. The present invention further relates to a method of capturing discharges from a source of discharges on a wearer's body in which at least a portion of the source of discharges is located within hydrous membranes having irregular surfaces (e.g., a female wearer's interlabial or intervaginal space).

25

BACKGROUND OF THE INVENTION

5 All manner and variety of absorbent articles configured for the absorption of body fluids such as menses, urine and feces are well known. With respect to feminine protection devices, the art has offered two basic types; sanitary napkins have been developed for external wear about the pudendal region while tampons have been developed for internal wear within the vaginal cavity for interruption of menstrual flow therefrom. Such tampon devices are disclosed in U.S. Patent No. 4,412,833, entitled "Tampon Applicator", issued to Weigner, et al. on November 1, 1983, and U.S. Patent No. 4,413,986, entitled "Tampon Assembly With Means For Sterile Insertion", issued to Jacobs on November 8, 1983.

15 Hybrid devices which attempt to merge the structural features of the sanitary napkins and the tampons into a single device have also been proposed. Such hybrid devices are disclosed in U.S. Patent No. 2,092,346, entitled "Catamenial Pad", issued to Arone on September 7, 1937, and U.S. Patent No. 3,905,372, entitled "Feminine Hygiene Protective Shield", issued to Denkinger on September 16, 1975. Other less intrusive hybrid devices are known as labial or interlabial sanitary napkins and are characterized by having a portion which at least partially resides within the wearer's vestibule and a portion which at least partially resides external of the wearer's vestibule. Such devices are disclosed in U.S. Patent No. 2,662,527, entitled "Sanitary Pad", issued to Jacks on December 15, 1953; U.S. Patent No. 4,631,062, entitled "Labial Sanitary Pad", issued to Lassen, et al. on December 23, 1986; and U.S. Patent No. 4,673,403, entitled "Method and Pad Allowing Improved Placement of Catamenial Devices", issued to Lassen, et al. on June 16, 1987.

Interlabial pads have the potential to provide even greater freedom from inconvenience because of their small size and reduced risk of leakage. Numerous

attempts have been made in the past to produce absorbent devices which would combine the best features of tampons and sanitary napkins while avoiding at least some of the disadvantages associated with each of these types of devices. Examples of such devices are described in U.S. Patent 2,917,049 issued to Delaney on December 15, 1959, U.S. Patent 3,420,235 issued to Harmon on January 7, 1969, U.S. Patent 4,595,392 issued to Johnson, et al. on June 17, 1986, and U.S. Patent 5,484,429 issued to Vukos, et al. on January 16, 1996. A commercially available interlabial device is the INSYNC Miniform interlabial pad which is marketed by A-Fem of Portland, OR and described in U.S. Patents 3,983,873 and 4,175,561 issued to Hirschman on October 5, 1976 and November 27, 1979, respectively.

Many of these devices have not met with great commercial success, however. There are drawbacks associated with all of the above products. For example, the device described in the Delaney patent does not appear to be capable of an easy and comfortable insertion, due to the possibility of the layers of absorbent material opening up during insertion. The commercially available IN-SYNC interlabial device suffers from the disadvantage that it may tend to allow by-pass flow around its edges. Such flow can cause body soiling or panty soiling which many consumers find unacceptable.

Improved interlabial devices are described in the following patents assigned to The Procter & Gamble Company: U.S. Patent 5,762,644; U.S. Patent 5,885,265; U.S. Patent 5,891,126; U.S. Patent 5,895,381; U.S. Patent 5,916,205; U.S. Patent 5,928,452; U.S. Patent 5,951,537; U.S. Patent 5,968,026; U.S. Patent 6,033,391; and, U.S. Patent 6,045,544. The search for improved interlabial devices has, however, continued. In particular, there is a need for improved, more comfortable, topsheets for such devices that contact the wearer's inner labia majora surfaces, and the skin within the vaginal vault.

Interlabial product have several expectations. First, products that are worn predominantly interlabially are expected to remain in place without any of the usual panty attachment approaches (i.e., adhesives). For such products to remain positioned within the labia they are required to adapt to the labial vault and remain fixed via a combination

of structural adaptation (i.e. fit) and physical interactions such as friction (i.e. slippage control) or adhesion due to capillary suction. Second, interlabial devices are also, due to their limited size (to be able to be accommodated within the labia), expected to collect bodily discharges as their source so as to minimize the risk of panty soiling that would occur if bodily discharges were able to move freely towards the perimeter of the labia and come into contact with the wearer's undergarments. Contrary to expectation providing a superior soiling experience, through better management of bodily discharges, for a product worn interlabially, is not a simple task. Products worn predominantly within the labia are closer to the discharge source but have a more complex task in managing bodily discharges than an externally worn sanitary napkin or internally worn tampon.

This complexity results from the anatomical complexity of the labial vault and the unique interaction of bodily discharges with the labial surface. First, the anatomical structure of the labial vault is complex and is not constant from one woman to another or one race to another. For example, the labial vault dimensions tend to increase in size being smaller in Asians, increasing on white Caucasians, and increasing further for Africans. Each group has a wide diversity of shapes, sizes, and depths. The non-constant labial vault provides a high degree of complexity given that a predominantly worn interlabial pad must physically contact and absorb the bodily discharge as it exits the vaginal opening. Additionally, the ability of a single product design to actually fit can be questionable because of the high degree of structural differentiation among women.

Even if a limited number of product designs can be made in such a way so as to fit a large number of unique labial shapes and sizes the product must provide uniform contact to all of the surfaces within the labial vault that may be covered with the transporting bodily discharges.

To solve this problem the product must have both the "macroscopic adaptability" and "microscopic adaptability" components. "Macroscopic adaptability" is the overall fit of the product within the labial vault. "Microscopic adaptability" is the fit of the interlabial product within the textured labial surface and extraction of bodily discharges from within this textured surface.

In addition, anatomically speaking, there are striking differences in both the physical structure and the properties of the skin within the labia, particularly the labia minora compared to adjacent skin surfaces such as in the perineal groove, buttocks and inner thigh regions that would normally be contacted by a sanitary napkin. It is important to differentiate between external surfaces (such as the buttocks, perineal grove, the outwardly facing labia majora surfaces) and internal surfaces (such as the labia minora, vulva vault, and the vagina). As one progresses from the "external" bodily surfaces of the buttocks or inner thighs, representative of a normal stratum cornea, towards the vulva the stratum cornea begins to change. The vulva majora (externally facing surfaces) still exhibits a stratum cornea but somewhat thickened and in a somewhat immune sensitized state indicative of a greater sensitivity to external influence. Nevertheless, such "external" skin types, macroscopically viewed, are still considered to be relatively smooth and dry to the touch. They are considered to be relatively hydrophobic in nature. They exhibit similar degrees of hydration to other bodily sites, similar friction coefficients (especially when absorbent materials are next to these tissues) and degrees of elasticity and compressibility that are all within a factor of three (see Elsner et al., *British Journal of Dermatology* (1990). Issue 122, p 607-614, and Elsner et al., *Dermatologica* (1990). Issue 181, p 88-91). Moving interlabially from the labia majora (moving to the internal bodily surfaces) to the labia minora and then internally (vaginal vault) a fundamental change in the properties of the skin or labial membrane occurs. The inner labial minora surfaces are starting to become more characteristic of a mucosa membrane than a stratum cornea. As one moves from the labial vault into the vaginal vault the transition is complete to a mucosa membrane. Tissues within the labial vault, especially the inward facing surfaces of the labia minora are permanently wet, are believed to have a significantly higher friction coefficient, elasticity, and compressibility. These membranes are highly textured (irregular surface) and are hydrophilic not hydrophobic.

Since the inner surfaces of the labial membrane is both hydrophilic and is highly textured it provides an ideal surface for transporting bodily discharges for two reasons. First, the inner surfaces of the labial membrane are hydrophilic and have a high affinity for blood or other bodily discharges. Secondly, the blood is able to move freely within

the textured surface within the naturally occurring channels that are present within the inner labial surfaces. This provides quite a challenge since products that are worn predominantly within the labia need to make close contact with the labial surface if they are to effectively absorb bodily discharges as their source. Blood can hide within these channels and has a high affinity for the inner labial membrane.

Ideally an absorbent core structure of an interlabial product would be highly adaptable, compressible, possesses an irregular structure, and able to effectively contact the inner labial surfaces and specifically the channels within the textured surface that can transport bodily discharges out of the labial vault and on to the wearers under garments.

In addition the absorbent core structure would be highly absorbent with a very high absorbent capacity per unit volume of core. High capacity in a small core size (or volume of absorbent material) is key to ensuring the product can be worn, predominantly interlabially, even if the labia is relatively small in dimensions and has little space available to hold the absorbent body. Furthermore, the absorbent body will need to actively compete with the hydrophilic inner labial surface for the bodily discharges the absorbent core would need to exhibit a very high suction gradient to positively attract discharges into the absorbent body and this gradient would need to be efficiently refreshed during the wearing cycle of the absorbent structure to ensure continued performance throughout the products wearing cycle.

Unfortunately, the solution of these two problems (via macroscopic and microscopic adaptability) introduces an additional problem. As the absorbent structure is made more adaptable and flexible so as to comfortably conform to each women's unique anatomical shape it becomes more difficult to reproducibly and correctly position the interlabially worn product within the labial vestibule (or for that matter within a vagina if the same techniques are applied for this application). In order to provide a controllable insertion into the labia a degree of stiffness and structural integrity is required in the absorbent product so as to part the labial minora, labia majora and extraneous tissue and achieve sufficient insertion depth within this vestibule. In fact achieving a controlled, reproducible placement of the product within the labia while achieving a high degree of

surface coverage via increased core adaptability are conflicting design requirements and generally speaking mutually incompatible.

To solve this conflicting set of requirements a need exists for an interlabial pad design composed of three key elements:

- 5 i.) A highly adaptable absorbent structure able to macroscopically adapt to a unique anatomical shape;
- ii.) Combined with a microscopically structured absorbent core/topsheet; and
- iii.) A robust application/insertion design feature either in the form of
10 an applicator or reinforced keel structure..

In addition to these aspects relevant to absorption of bodily discharges the absorbent core structure is required to be highly flexible so as to adapt to the unique shape and surface structure of each particular wearer without being uncomfortable.

Therefore, a need exists for an absorbent core structure for a product that is worn
15 predominantly within the labia that is able to effectively meet these needs has been developed and is composed of three distinct elements:

- 1) A highly absorbent storage core element composed of absorbent gelling material (AGM). Since AGM provide a high absorption suction potential and are more
20 efficient (up to 3x higher capacity per gram of material with blood) at storing than classical materials (i.e. cotton, rayon) and facilitate the use of a less bulky absorbent core.
- 2) The use of a simple high-loft body contacting and discharging acquiring layer on the body side of the AGM containing absorbent core. The high loft fibrous layer is
25 compressible, adaptive and can adjust to conform to the inner labial surface texture to fill in the various channels that may be transporting or collecting bodily discharges.

- 3) A needle punching technique that serves to both combine these two layers and dramatically improve the core efficiency and amount of bodily discharge that the storage core can accommodate.

Further products that are worn predominantly interlabially are often sufficiently small so as to potentially be toilet flushable as a hands off disposal method (ejection during urination).

Traditionally, on externally worn absorbent articles (contacting predominantly "external" bodily surfaces) such as sanitary napkins, a hydrophilic topsheet or hydrophobic topsheets treated to be hydrophilic (such as with a surfactant) have been utilized to ensure adequate absorption and transmission of bodily discharges to the absorbent core structure. There has been a significant number of disclosures on approaches to create soft, performing topsheets for use externally and in contact with dry and relatively smooth skin surfaces such as in the perineal groove, buttocks and inner thigh regions.

In the case of internally worn disposable absorbent products (contacting predominantly "internal" bodily surfaces), traditionally absorbent and hydrophilic topsheets and particularly rayon based topsheets (delivering biodegradability and softness) have been chosen such that the products can be disposed of by flushing down a toilet. Such topsheets (particularly rayon webs) have also been utilized for hybrid absorbent products that are either partially or wholly worn within the labial vault. However, the applicants have discovered that traditional hydrophilic and particularly absorbent hydrophilic topsheets are not ideally suited for internal and particularly interlabially worn absorbent products, and in fact may contribute significantly to discomfort and perceptions of soreness and irritation while wearing such products in use. This seems to be contrary to the known art that would expect soft, smooth, hydrophilic topsheets such as rayon or many nonwovens to be ideal candidates for a general feminine absorbent article.

This conflict with prior art can perhaps be understood if we consider an interlabially worn absorbent pad with an absorbent, hydrophilic topsheet such as a rayon web. On placing such a product within the labia and specifically in contact with the "internal" facing surfaces of the labial minora, such topsheets are able to absorb labial secretions. Apart from tending to dry the labial membrane (one source of discomfort and irritation) the topsheet has a natural tendency to adhere to the labial membrane via hydrophilic-hydrophilic compatibility. This establishes yet another source of discomfort as the labial membrane is very elastic and is expected to deform/freely move with bodily motion and with respect to each other. If an absorbent product is attaching to this membrane and is unable to move to the same degree of elasticity, a process of adhere-shear is set up during bodily motion that creates a level of discomfort (rough, dry rubbing sensations) for the products user.

Several approaches have been attempted to provide improved, more comfortable topsheets for such products. European Patent Application 0 685 215 A1 is directed to a "Vaginal moisture balanced tampon and process." This publication is directed toward reducing vaginal epithelium drying by reducing the capillary suction pressure of a tampon in early use. This is said to be accomplished by modifying the capillary suction pressure of the surface of the tampon by using hydrophobic components in the tampon, such as hydrophobic fibers and/or a hydrophobic cover material. Other means of obtaining a lower capillary suction pressure are said to include increasing the denier of the fibers in the tampon's absorbent core and/or decreasing the density of the tampon.

U.S. Patent 4,846,824, Lassen, et al., entitled "Labial Sanitary Pad" describes another approach. The Lassen '824 patent indicates that the use of a physiologically hydrous cover maintains the ideal level of moisture within the urogenital region. The term "physiologically hydrous" is said to connote a cover material that maintains a suitably moist interface between the tissues of the vestibule and the pad when disposed in the vestibular environment. An example of a highly preferred cover in the Lassen '824

patent is one made from a spunlaced polyester such as that sold under the tradename "SONTARA" by E. I. DuPont Company.

Therefore, a need exists for improved devices which are worn adjacent to a wearer's hydrous body tissues, such interlabial device which will reduce the incidence of body and panty soiling when used. In particular, a need exists for improved, more comfortable, topsheets for such devices that contact the wearer's inner labia majora surfaces, and the skin within the vaginal vault. Such a device should be easy to insert and be comfortable during wear. Preferably, such a device will be comfortable enough for everyday use, if desired. A need also exists for an improved interlabial device which has sufficient capacity to serve as a stand alone product during the heavy flow days of a wearer's menstrual period, and is not subject to the problem of falling out of the interlabial space when loaded to its absorbent capacity. A need also exists for other types of absorbent devices such as sanitary napkins, tampons, pantliners, interlabial devices, incontinence devices, and bandages, which have such a topsheet.

SUMMARY OF THE INVENTION

The present invention relates to an improved body-contacting surface or topsheet for absorbent devices that come into contact with a wearer's hydrous body tissues. These hydrous body tissues may include, but are not limited to hydrous tissues such as interlabial skin or tissue and mucosal tissues such as vaginal tissues. In one non-limiting embodiment, the topsheet comprises a non-absorbent, moderately hydrophilic to substantially hydrophobic nonwoven web. The topsheet can have a critical surface tension of less than or equal to about 45 dynes/cm, preferably less than or equal to about 40 dynes/cm. In one embodiment, the nonwoven web has been mechanically modified so that it is extensible in at least one direction in an amount greater than or equal to about 30% under a force of 50 grams. The topsheet preferably undergoes a caliper change of greater than or equal to about 30% under a pressure of 1,000 Pa after being subjected to a pressure of 250 Pa. The topsheet is placed on absorbent devices such as sanitary napkins, tampons, pantliners, interlabial devices, incontinence devices, bandages, and other articles.

The present invention also relates to absorbent devices such as sanitary napkins, tampons, pantliners, interlabial devices, incontinence devices, bandages, and other articles which have such an improved topsheet. The term "interlabial device" refers to an absorbent device that is at least partially insertable into the interlabial space of a female
5 wearer for catamenial purposes (including menses and mid-cycle discharges), incontinence protection (including urine), or both.

The present invention further relates to a method of capturing discharges from a source of discharges on a wearer's body in which at least a portion of the source of discharges is located within hydrous membranes having irregular surfaces (e.g., a female
10 wearer's interlabial or intervaginal space). The method comprises: providing an absorbent article having a liquid pervious top surface structure, said top surface structure having a body contacting surface, wherein said top surface structure has at least regions that are extensible; and placing the absorbent article adjacent to the hydrous membranes of a wearer's body, with the body-contacting surface of the top surface structure at least
15 partially in contact with the hydrous membranes.

The absorbent device utilizing the topsheet can be of any suitable structure known in the art, or it may be of a novel structure. The absorbent interlabial device, in one non-limiting embodiment, is a small pad-like structure that comprises a liquid pervious topsheet, a liquid impervious backsheet which is joined to the topsheet, and an absorbent
20 core positioned between the topsheet and backsheet. The device preferably comprises an axis of preferred bending, preferably located generally along the longitudinal centerline of the device. When the device is folded along this axis and inserted into the wearer's interlabial space, the topsheet maintains contact with the walls of the wearer's labia. Preferably, the device comprises biodegradable materials. In some embodiments, the
25 backsheet of the absorbent interlabial device is water dispersible. In other embodiments, the backsheet can be eliminated. The backsheet can be eliminated if the underside of the absorbent core is coated. Alternatively, the backsheet can be eliminated if the device is primarily contained within the labia, and the interlabial device is folded along a longitudinal axis. In such a case, the device assumes an inverted V or U-shaped cross-sectional structure, and the portions of the device which would normally be provided with
30 a backsheet will face inward toward each other, and will not contact a wearer's garments. The elimination of a backsheet will improve the breathability of the device. A tab may be joined to the underside of the device to facilitate insertion and optional removal of the device with the fingers.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with claims particularly pointing out and distinctly claiming the subject matter which is regarded as forming the present invention, it is believed that the invention will be better understood from the following description taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a top plan view of a preferred embodiment of the absorbent interlabial device according to the present invention.

FIG. 2 is a cross sectional view of the absorbent interlabial device shown in FIG. 1, taken along line 2-2 of FIG. 1.

FIG. 3 is a side view of the absorbent interlabial device shown in FIG. 1.

FIG. 4 shows the absorbent interlabial device shown in FIG. 1 folded along the axis of preferred bending and being grasped for insertion by the wearer's fingers.

FIG. 5 is a cross-sectional sagittal view of a human female wearer showing the placement of the absorbent interlabial device in the wearer's interlabial space.

FIG. 6 is a photomicrograph of a portion of one embodiment of a topsheet according to the present invention.

FIG. 7 is a simplified illustration of an apparatus used to form a strainable network into the topsheet base material.

FIG. 8 is a segmented schematic perspective illustration of a portion of a web of material having a strainable network formed therein.

FIG. 9 is a scan of the surface of the topsheet material shown in FIG. 6.

FIG. 10 is a scan of a prior art rayon nonwoven topsheet material.

FIG. 11 is a graph of the surface area of various materials measured at various depths below the plane of their top surface.

FIG. 12 is a perspective view of an interlabial device.

FIG. 13 is a schematic side view showing a portion of the absorbent structure of the interlabial device shown in FIG. 12.

FIG. 14 is a schematic side view showing a portion of an alternative topsheet that has a plurality of ridges and valleys therein, and a substance for maintaining the topsheet in contact with a wearer's body located on at least some of the ridges on the body-contacting surface of the topsheet.

FIG. 15 is a prior art sanitary napkin which may be used in a method of using a system of feminine hygiene products or as part of a feminine protection kit with the absorbent interlabial device of the present invention.

FIG. 16 is a typical prior art tampon which may be used in a method of using a system of feminine hygiene products or as part of an additional feminine protection kit with the absorbent interlabial device of the present invention.

FIG. 17 is a plan view of an apparatus suitable for flushability determination according to the method described in the TEST METHODS section, below.

FIG. 18 is a cross-section of the flushability apparatus of FIG. 17 taken along line 18--18 thereof.

FIG. 19 is a simplified illustration of the basic elements of a needlepunch machine.

FIG. 20 is a plan view of an interlabial device containing cross machine direction slitting.

FIG. 21 is a plan view of an interlabial device containing folding lines in multiple sections.

FIG. 22 is a plan view of an interlabial device where the interlabial core of the interlabial device is divided into sections.

FIG. 23 is a table showing data evaluating the ability to control soiling when used as a menstrual product and their level of comfort when worn for menstrual use.

FIG. 24 is a picture of the beginning of the V Bend test used to test the longitudinal stiffness of the interlabial product.

FIG. 25 is a picture of the V Bend test used in the process of testing the longitudinal stiffness of the interlabial product.

FIG. 26 is a picture of the beginning of the Free V Bend test used to test the longitudinal stiffness of the interlabial product.

5 FIG. 27 is a picture of the Free V Bend test used in the process of testing the longitudinal stiffness of the interlabial product.

FIG. 28 is a picture of the beginning of the L Bend test used to test the resistance of an interlabial product to deform along its cross direction centerline.

10 FIG. 29 is a picture of the L Bend test used in the process of testing the resistance of an interlabial product to deform along its cross direction centerline.

FIG. 30 is a picture of the beginning of the Keel Stiffness test used to test the stiffness of an affixed insertion/application controlling member.

FIG. 31 is a picture of the Keel Stiffness test used in the process of testing the stiffness of an affixed insertion/application controlling member.

15 FIG. 32 is a graph indicating the increase in the absorbent capacity resulting from needle-punching.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to an improved body-contacting surface or topsheet for absorbent articles or devices, and more particularly to a topsheet that is comfortable when it is placed in contact with hydrous body tissues. The present invention also relates to absorbent devices such as sanitary napkins, tampons, pantliners, interlabial devices, and incontinence devices, which have such a topsheet. The present invention further relates to a method of capturing discharges from a source of discharges on a wearer's body in which at least a portion of the source of discharges is located within hydrous membranes having irregular surfaces (e.g., a female wearer's interlabial or intervaginal space).

FIGS. 1-5 show one non-limiting example of an absorbent interlabial device, interlabial device 20 that may be provided with the improved topsheet 42 described herein. The present invention, however, is not limited to use on a structure having the particular configuration shown in the drawings.

5 As used herein, the term "absorbent interlabial device" refers to a structure which has at least some absorbent components, and which is specifically configured to reside at least partially within the interlabial space of a female wearer during use. Preferably, when the absorbent interlabial device 20 is properly sized for an individual wearer, at least about half of the entire absorbent interlabial device 20 of the present invention
10 resides within such interlabial space. More preferably, substantially the entire absorbent interlabial device 20 resides within such interlabial space, and most preferably the entire absorbent interlabial device 20 resides within such interlabial space of a female wearer during use.

As used herein, the term "interlabial space" refers to that space in the pudendal
15 region of the female anatomy which is located between the inside surfaces of the labia majora extending into the vestibule. Located within this interlabial space are the labia minora, the vestibule and the principal urogenital members including the clitoris, the orifice of the urethra, and the orifice of the vagina. Standard medical authorities teach that the vestibule refers to the space bounded laterally by the inside surfaces of the labia
20 minora and extending interiorly to the floor between the clitoris and the orifice of the vagina. Therefore, it will be recognized that the interlabial space as defined above may refer to the space between the inside surfaces of the labia majora, including the space between the inside surfaces of the labia minora also known as the vestibule. The interlabial space for purposes of the present description does not extend substantially
25 beyond the orifice of the vagina into the vaginal interior.

The term "labia" as used herein refers generally to both the labia majora and labia minora. The labia terminate anteriorly and posteriorly at the anterior commissure and the posterior commissure, respectively. It will be recognized by those skilled in the art that

there is a wide range of variation among women with respect to the relative size and shape of labia majora and labia minora. For purposes of the present description, however, such differences need not be specifically addressed. It will be recognized that the disposition of the absorbent interlabial device into the interlabial space of a wearer as defined above will require placement between the inside surfaces of the labia majora without regard to the precise location of the boundary between the labia majora and the labia minora for a particular wearer. For a more detailed description of this portion of the female anatomy, attention is directed to *Gray's Anatomy*, Running Press 1901 Ed. (1974), at 1025-1027.

The absorbent interlabial device 20 shown in FIG. 1 has a longitudinal centerline L which runs along the "x" axis. The term "longitudinal", as used herein, refers to a line, axis or direction in the plane of the interlabial device 20 that is generally aligned with (e.g., approximately parallel to) a vertical plane which bisects a standing wearer into left and right body halves when the interlabial device 20 is worn. The terms "transverse," "lateral," or "y direction" as used herein, are interchangeable, and refer to a line, axis, or direction that is generally perpendicular to the longitudinal direction. The lateral direction is shown in FIG. 1 as the "y" direction. The absorbent interlabial device 20 shown in FIG. 1 also has a transverse centerline T. The "z" direction, shown in FIG. 2, is a direction parallel to the vertical plane described above. The term "upper" refers to an orientation in the z-direction toward the wearer's head. "Lower" or "downwardly" is toward the wearer's feet.

The interlabial device 20 shown in FIGS. 1-3 is in one preferred configuration. The interlabial device 20 has a body-facing (or "body-contacting" side) 20A and an opposed underside 20B. The interlabial device comprises a pad-like main body portion (or "central absorbent portion") 22 and an optional placement and removal tab 52 which is joined to the underside 20B of the main body portion 22 to provide the overall interlabial device with a "T"-shaped cross-sectional configuration. The main body portion 22 can be in any suitable configuration. Non-limiting examples of shapes for the

main body portion 22 when viewed from the top as in FIG. 1 include ovoid, elliptical, trapezoidal, rectangular, triangular, diamond-shaped, or any combination of the above. As shown in FIG. 1, the preferred plan view shape for the main body portion 22 and the overall absorbent interlabial device 20 is generally ovoid or elliptical. The plan view
5 shape of the main body portion 22 tapers from the transverse centerline T towards its front and rear ends. The main body portion 22, in this embodiment, is relatively flat in its side profile, but may taper slightly from front to rear as shown in FIG. 3.

As shown in FIGS. 1-2, the interlabial device preferably comprises a liquid pervious topsheet 42, a liquid impervious backsheet 38 joined to the topsheet 42, and an
10 absorbent core 44 positioned between the topsheet 42 and the backsheet 38. The interlabial device 20 is preferably of a size and shape that allows at least the majority of the device 20 to fit comfortably within the wearer's interlabial space and to cover the wearer's vaginal orifice, and preferably also the wearer's urethra. The interlabial device 20 at least partially blocks, and more preferably completely blocks and intercepts the flow
15 of menses, urine, and other bodily exudates from the wearer's vaginal orifice and urethra.

The size of the interlabial device 20 is important to its comfort and effectiveness. The length of the absorbent interlabial device 20 is measured along the longitudinal centerline L in the longitudinal direction (or "x"-direction). The absorbent interlabial device 20 preferably has a length L_1 which is greater than about 40 mm and less than
20 about 130 mm. More preferably, the length L_1 is between about 60 mm and to about 100 mm. The width of the interlabial device 20 is measured along the transverse centerline T in the transverse direction (or "y"-direction). The absorbent interlabial device 20 preferably has a width W_1 which is between about 25 mm and about 60 mm. The thickness (or caliper) is the "z"-direction dimension of the main body portion of the
25 device 20. Caliper measurements given herein were measured using an AMES gauge with a 0.25 psi (1.7 kPa) (gauge) load and a 0.96 inch (2.44 cm) diameter foot. Those skilled in the art will recognize that if a 0.96 inch (2.44 cm) diameter foot is not appropriate for a particular sample size, the foot size may be varied while the load on the

gauge is accordingly varied to maintain a confining pressure of 0.25 psi (1.7 kPa) (gauge). The caliper T_1 of the main body portion of the absorbent interlabial device 20 is preferably less than the width W_1 and the length L_1 of the device 20. Preferably, the caliper T_1 of the main body portion of the absorbent interlabial device 20 is less than or equal to about 8 mm, more preferably the caliper T_1 is less than or equal to about 6 mm, and even more preferably the caliper is less than or equal to about 4 mm.

The main body portion 22 of the interlabial device 20 is preferably also flexible, more preferably relatively highly flexible, but not so flexible that it will be difficult to insert. This will increase the wearing comfort of the interlabial device 20. The main body portion 22 of the interlabial device 20 preferably has a flexure resistance within the ranges disclosed in U.S. Patent 5,951,537 issued to Osborn on September 14, 1999.

The below section will detail design details for improving IL fit within the labia and a more controlled insertion to achieve a deeper fit within the labia vestibule. The microscopic fit will be described in the needle punched core documents.

Construction of the absorbent interlabial device 20 according to the particular size parameters given above results in a product with increased comfort and effectiveness compared to previous interlabial devices. For example, many women find interlabial pads which are shorter than the absorbent interlabial device 20 described herein to be difficult to position properly within the interlabial space. Even if such pads are positioned properly, they have an increased tendency to allow by-pass flow of body exudates around the edges of the pad.

The interlabial device 20 is preferably provided with sufficient absorbency to absorb and retain the exudates discharged from the wearer's body. The capacity of the product, however, is dependent at least partially upon the physical volume of the absorbent interlabial device 20. The absorbent interlabial device preferably has a capacity of at least about 1 g of 0.9% by weight saline solution, and may have a capacity of up to about 30 g by using absorbent gels or foams that expand when wet. Preferably, capacities typically range from about 2 to about 12 grams, for saline. More preferably, the capacity

of the device 20 is greater than or equal to about 6 g for saline. Those skilled in the art will recognize that the capacity for absorption of body exudates such as menses will typically be smaller than the capacities given above for absorption of saline. A method for measuring absorbent capacity is described in the Test Methods section, below. Since the interlabial space can expand, larger volumes can be stored in the interlabial space, particularly if the fluid is stored as a gel, which adjusts to the body pressures. Additionally, if the absorbent interlabial device 20 does not reside completely within the wearer's interlabial space, some of the absorbed exudates may be stored externally to the wearer's interlabial space.

The individual components which may be suitable for the various embodiments of the interlabial device 20 will now be looked at in greater detail with reference to FIGS. 1 - 32. The following components of the interlabial device will be described in the following manner: topsheet, absorbent core, slits, acquisition layer, backsheet, insertion means, and other alternative embodiments of the interlabial device.

TOPSHEET

The topsheet 42 comprises a first liquid pervious component. The topsheet 42 is liquid pervious, permitting liquids (e.g., menses and/or urine) to readily penetrate through its thickness. It should be understood that when the topsheet 42 is described herein as being liquid pervious, if the topsheet is not liquid pervious on its own, this liquid perviousness will be considered to be present if the topsheet is used in conjunction with another layer, such as an underlying layer which draws liquids through the topsheet. The topsheet 42 should be compliant, soft feeling, and non-irritating to the wearer's skin. In particular, a topsheet which is used on absorbent devices that come into contact with a wearer's hydrous body tissues, should even be more comfortable. These hydrous body tissues may include, but are not limited to hydrous tissues such as interlabial skin or tissue and mucosal tissues such as vaginal tissues.

A suitable topsheet 42 may be manufactured from a range of materials such as woven and nonwoven materials; polymeric materials such as apertured formed thermoplastic films, apertured plastic films, and hydroformed thermoplastic films; porous foams; reticulated foams; reticulated thermoplastic films; and thermoplastic scrims.

5 Suitable woven and nonwoven materials can be comprised of natural fibers (e.g., hydrophobically-treated wood, rayon, or cotton fibers), synthetic fibers (e.g., polymeric fibers such as polyester, rayon, polypropylene, or polyethylene fibers) or from a combination of natural and synthetic fibers. If the topsheet comprises a nonwoven material, it can be made by any suitable process. For example, it can be carded,
10 spunbonded, etc.

The topsheet materials described above (woven, nonwoven, films, etc.) can be made from biodegradable materials, or non-biodegradable materials. As used herein, the term "biodegradable materials" refers to materials having greater than or equal to about 70% biodegradation (percentage of theoretical carbon dioxide evolution) after 28 days
15 when measured according to the Sturm Test which has been designated Method 301B by the Organization for Economic Cooperation and Development, 2 rue Andre Pascal, 75775 Paris Cedex 16, France. Preferably, the materials comprising the interlabial device of the present invention have a biodegradation of greater than about 80% and, more preferably, biodegradation is greater than or equal to about 90%.

20 The topsheet 42 should be provided with the improved properties described herein so that it will be more comfortable for contacting the wearer's hydrous body tissues. The topsheet preferably comprises a non-absorbent, moderately hydrophilic to substantially hydrophobic material. The topsheet preferably has a critical surface tension of less than or equal to about 45 dynes/cm, more preferably less than or equal to about 40 dynes/cm.
25 The critical surface tension should be measured according to the Material Critical Surface Tension test in the Test Methods section. In preferred embodiments, the topsheet is made as hydrophobic as possible to reduce the tendency for it to adhere to the hydrous body tissues.

The topsheet 42 should preferably be compressible and resilient so that it is comfortable when placed adjacent to the wearer's hydrous body tissues. The compressibility is preferably measured under loads typically encountered when wears a product having the topsheet thereon. The topsheet preferably undergoes a caliper change of greater than or equal to about 30% under a pressure of 1,000 Pa after being subjected to a pressure of 250 Pa. The topsheet 42 preferably undergoes an absolute caliper change of greater than or equal to about 0.15 mm under a pressure of 1,000 Pa after being subjected to a pressure of 250 Pa. The topsheet compressibility should be measured using the Topsheet Compressibility (Thickness Change) test described in the Test Methods section.

The topsheet 42 is preferably also extensible so that it will be capable of extending with the movements of the wearer's body, and specifically with the movements of the wearer's hydrous body tissues. Anatomically speaking, the wearer's labia resides in a relatively low motion zone of the body. Even though the extent the labia is expected to elongate as a result of motion is relatively low, due to the high extensibility of the labial membrane, the topsheet preferably elongates as required with minimal forces. The topsheet is preferably extensible in at least one direction in an amount greater than or equal to about 30% under a force of 50 grams. The topsheet 42 may be extensible in one direction, in two directions, in multiple directions, or in all directions (i.e., it may be omni-directionally extensible).

In other embodiments, a topsheet 42 may be provided which is comfortable when one of the qualities quantified herein is lower than set forth herein, if one of the other qualities of the topsheet quantified herein is increased. For instance, in one non-limiting example, the topsheet 42 may have a different combination of compressibility and extensibility, if desired. For example, a suitable topsheet may have an extensibility in at least one direction of greater than or equal to about 20% under a force of 50 grams, and the topsheet may undergo a caliper change of greater than or equal to about 40% when tested according to the Topsheet Compressibility/Thickness Change Test.

The starting materials (or base materials) described above may need to be altered or modified (mechanically, chemically, or otherwise) to provide them with these properties.

In one embodiment, the topsheet can be formed of a web that has been mechanically modified to provide it with these properties. FIG. 6 shows one suitable topsheet 42 for use in the present invention. The topsheet shown in FIG. 6 is a mechanically altered spunbonded nonwoven material comprised of polyethylene fibers which has a basis weight of 23 grams/m². The fibers preferably have a relatively fine denier, preferably less than or equal to about 5, more preferably less than or equal to about 3. One preferred base material having these properties, is known as COROLIND nonwoven material, which is obtained from BBA Nonwovens (formerly Corovin GmbH) of Piene, Germany under the tradename PE HPC-2, code T23FOR. Such a material is then mechanically altered as described herein. Another suitable topsheet 42 can be a mechanically altered nonwoven web comprised of BIONELLE 3001 biodegradable fibers obtained from Showa Hugh Polymer Co. of Tokyo, Japan. These nonwoven materials can be mechanically altered by ring rolling or by forming a strainable network therein to form the topsheet 42.

In the embodiment shown in FIG. 6, the nonwoven material is mechanically altered by forming a strainable network therein. The strainable network is formed by a process which may be referred to herein as forming the topsheet base material into a stretchable elastic-like film (or "SElFing" the topsheet base material). This acronym will be used, although in the present case, it is to be understood that the topsheet base material (and the structure formed by SElFing the same) are not limited to films. That is, other materials, such as nonwovens can be subjected to the process for forming a strainable network therein.

A suitable process for forming a strainable network into the topsheet 42 is described in U.S. Patent 5,518,801 entitled "Web Materials Exhibiting Elastic-Like Behavior" which issued to Chappell, et al. on May 21, 1996. FIG. 7 is a simplified

illustration of an apparatus used to form a strainable network into the topsheet base material. The apparatus 700 shown in FIG. 7 comprises a pair of intermeshing toothed rolls 702 and 704. In one non-limiting embodiment, the SELFing process utilizes generally triangular-shaped "teeth" 706 that are rounded at the top. The teeth 706 used to
5 create the embodiments shown in FIG. 6 are 2.5 mm in height, and are spaced so that the peaks of the teeth are 0.6 mm apart, and there are 6.5 teeth per cm. The rolls 702 and 704 may have bands 708 around their circumference that are not provided with teeth 706 in order to leave an unformed region in the base material.

FIG. 8 is a segmented schematic perspective illustration of a portion of a web of
10 material having a strainable network formed therein. This web is shown as being made from a continuous, planar base material (similar to the way in which a film would appear), rather than a plurality of fibers as are nonwoven materials. This was done so that the pattern of the strainable network would be more visible. As shown in FIG. 8, the strainable network comprises a plurality of corrugations 66 that define ridges and valleys.
15 The corrugations 66 are separated by a generally planar region 64 that is oriented perpendicular to the ridges and valleys. The web material having the strainable network therein is extensible in the direction of the arrows.

As shown in FIG. 6, when the nonwoven material has just been subjected to the SELFing process, it has an appearance that looks similar to the schematic illustration
20 shown in FIG. 8. However, after handling, processing and assembling the SELFed nonwoven material into the interlabial device, the nonwoven topsheet loses some of its corrugated character and is less able to maintain this appearance (or clearly defined corrugated structure). Nevertheless, without this clear definition, the ability of the nonwoven to deform under compression and motion are still present. While the
25 compression and flexibility characteristics are less than those of a SELFed film, the SELFed nonwoven material has been found to be considerably more comfortable.

Applying a SELFing technique to the nonwoven web delivers a significant comfort improvement. Without wishing to be bound by any particular theory, the

SELFing process imparts structure (hills and valleys), reducing the overall surface area of topsheet in contact with the hydrous body tissues (in this case, the labial membrane). In addition, the SELFing imparts stretchability, compressibility and opens the web up thereby reducing capillary suction via increasing the fiber-fiber distances so that the areas of the topsheet that do actually interact with the labial membrane (via capillary suction) are more free to adapt with the labial membrane without exerting capillary suction on these portions of the labial membrane. Such mechanical treatments provide micro slippage points that significantly reduce the usual adhere-shear process (tendency of the topsheet to adhere to the body, and then be sheared from contact with the body) during bodily motion that drives discomfort while wearing a pad interlabially.

Alternative processes for ring rolling or "pre-corrugating" the base material are described in U.S. Patent 4,107,364 issued to Sisson on August 15, 1978; U.S. Patent 4,834,741 issued to Sabee on May 30, 1989, U.S. Patent 5,143,679 issued to Gerald M. Weber, et al. on September 1, 1992, U.S. Patent 5,156,793 issued to Kenneth B. Buell, et al. on October 20, 1992, and U.S. Patent 5,167,897 issued to Gerald M. Weber, et al. on December 1, 1992.

The webs which are used for the starting materials can be ring rolled or SELFed in one or more directions. For example, the webs can be ring rolled or SELFed in both the longitudinal and transverse directions (in the finished product). If the webs are ring rolled or SELFed in one direction, they will be extensible in one direction (perpendicular to the corrugations). If the webs are ring rolled or SELFed in two directions, they will be extensible in two directions. The embodiment shown in FIG. 6 is SELFed in only one direction.

Another suitable type of topsheet 42 comprises a mechanically altered (using SELFing or ring rolling) apertured formed film. Apertured formed films are pervious to body exudates and, if properly apertured, have a reduced tendency to allow liquids to pass back through and rewet the wearer's skin. Thus, the surface of the formed film which is in contact with the body remains dry, thereby reducing body soiling and creating a more

comfortable feel for the wearer. Suitable formed films that may be mechanically altered to form a more comfortable topsheet are described in U.S. Patent 3,929,135, entitled "Absorptive Structures Having Tapered Capillaries", which issued to Thompson on December 30, 1975; U.S. Patent 4,324,246 entitled "Disposable Absorbent Article Having
5 A Stain Resistant Topsheet", which issued to Mullane, et al. on April 13, 1982; U.S. Patent 4,342,314 entitled "Resilient Plastic Web Exhibiting Fiber-Like Properties", which issued to Radel, et al. on August 3, 1982; U.S. Patent 4,463,045 entitled "Macroscopically Expanded Three-Dimensional Plastic Web Exhibiting Non-Glossy Visible Surface and Cloth-Like Tactile Impression", which issued to Ahr, et al. on July 31, 1984; U.S. Patent
10 4,637,819 entitled "Macroscopically Expanded Three-Dimensional Polymeric Web for Transmitting Both Dynamically Deposited and Statically Contacted Fluids From One Surface to the Other", which issued to Ouellette, et al. on January 20, 1987; U.S. Patents 4,609,518 and 4,629,643 both issued to Curro, et al. on September 2, 1986 and December 16, 1986, respectively; U.S. Patent 5,006,394 entitled "Multilayer Polymeric Film" issued
15 to Baird on April 9, 1991; and U.S. Patent Application Serial No. 08/442,935 entitled "Fluid Transport Webs Exhibiting Surface Energy Gradients" filed in the name of Ouellette, et al. on May 31, 1995 (PCT Publication WO 96/00548, published January 11, 1996).

FIG. 9 is a scan of the surface of the topsheet material shown in FIG. 6. FIG. 9
20 shows that the topsheet material of a preferred embodiment described herein has an irregular and three dimensional character to its surface. This can be contrasted with FIG. 10, which is a scan of a prior art rayon nonwoven topsheet material. The three dimensional surface structure of the topsheet material shown in FIG. 9 provides the same with relatively high compressibility at the relatively low forces described above. The
25 surface of the prior art rayon nonwoven topsheet material shown in FIG. 10 differs in that it is generally regular and planar. The prior art rayon material is relatively incompressible under the forces specified herein.

FIG. 11 is a graph of the surface area of various materials measured at various depths below the plane of their top surface that quantifies the three dimensional character of the topsheet. The graph is a Bearing Ratio plot of various materials which can be measured according to the Surface Roughness Procedure described in the Test Methods section. This procedure takes a plane through the materials at various depths below a plane placed adjacent the highest points of the body-contacting surface of the material. A measurement is taken of the amount of the surface of the material that lies above the plane at this depth. Several topsheet materials are depicted in FIG. 11: the SELFEd COROLIND nonwoven material described above; the ring rolled (RR) BIONELLE biodegradable fiber nonwoven material described above; a hydroformed apertured film, which has not been mechanically altered following hydroforming; a nonwoven material known as "P-9", which has been micrexed; a flat (non-mechanically altered) COROLIND nonwoven material; and a flat rayon nonwoven material.

As shown in FIG. 11, the amount of surface area of the SELFEd COROLIND nonwoven material and the ring rolled BIONELLE topsheet material that lies above a plane that passes through these topsheets at a depth of 300 microns below the plane that passes through the highest points of their body-contacting surfaces is less than or equal to about 15% of the surface area of these topsheets as defined by the Bearing Ratio. Thus, there is much more topsheet surface area below this depth, indicating highly three-dimensional structures. The topsheets for contacting the wearer's hydrous body tissues can also be defined in that the amount of surface area that lies above a plane that passes through these topsheets at a depth of 400 microns is less than or equal to about 40%.

The topsheet 42 can be provided with at least one aperture 50 which is formed therein (that is, in addition to the spaces between the fibers of the nonwoven web) to assist in acquisition of liquids into the interlabial device 20. Preferably, the topsheet 42 is provided with a plurality of apertures. The apertures 50 can be of any suitable size and shape. There can be any suitable number of apertures. The apertures 50 can be arranged in any suitable pattern. In some embodiments, it is desirable for the apertures 50 to be

distributed in an acquisition area or zone 54. The acquisition zone 54 may be of any size, but preferably occupies less than or equal to about 30% of the available absorbent surface area. The apertures 50 have a combined open area that may be any suitable percentage of the acquisition zone 54, but preferably, the combined open area of the apertures 50 is greater than or equal to 10% of the area of the acquisition zone 54. There may also be apertures outside the acquisition zone 54. Preferably, the combined open area of the apertures 50 in the acquisition zone 54 is greater than the combined open area of any apertures in the area outside the acquisition zone 54.

For purposes of illustration, Fig. 1 shows that in one non-limiting embodiment, there are twenty-six circular apertures 50, each approximately 2 mm in diameter. The apertures 50 are arranged in diagonal relationship with each other in an acquisition zone 54 that is elliptically shaped, similar to the shape of the outer edge of the interlabial device 20. In this embodiment, the absorbent core 44 surface area is approximately 2490 mm². The area of the acquisition zone 54 is approximately 520 mm². The acquisition zone 54, thus, occupies less about 21% of the available absorbent core surface area. The combined open area of the apertures 50 is 82 mm². The combined open area of the apertures 50 is about 16% of the area of the acquisition zone 54.

In another non-limiting embodiment, the apertures 50 are arranged in two longitudinally-oriented rows, one on each side of the longitudinal centerline L. There can be any suitable number of apertures in these rows. For example, these rows can be centered about the transverse centerline, T, with seven apertures in each row.

The apertures 50 can be formed in the topsheet 42 prior to assembling one or more of the components of the absorbent article, or after assembling one or more of the components of the absorbent article. For example, the apertures 50 can be formed in the topsheet material alone, and the topsheet 42 can then be joined to the other components of the absorbent article. In other embodiments, the topsheet 42 can be joined to one or more components, and the topsheet 42 and the component(s) to which it is joined are all apertured at the same time. Preferably, the apertures 50 are formed after the topsheet 42

is joined to the absorbent core 44, and both the topsheet 42 and absorbent core 44 have apertures 50 formed therein.

The topsheet 42 is preferably joined to the other components of the absorbent article in a manner so that the topsheet maintains its ability to stretch in response to the motions of the wearer's body. The inner surface of topsheet 42 may be secured in contacting relation with an underlying absorbent layer. This contacting relationship results in liquid penetrating topsheet 42 faster. The topsheet 42 may be kept in a contacting relationship with an underlying layer by bonding the topsheet 42 to the underlying layer. However, it is not absolutely necessary to bond the face of the topsheet 42 to the face of the underlying layer. The topsheet 42 can be maintained in contact with an underlying absorbent component by entangling the fibers of the underlying layer with the topsheet, by fusing the topsheet 42 to an underlying absorbent layer by a plurality of discrete individual fusion bonds, or by any other means known in the art. The topsheet can also be maintained in contact with the underlying absorbent material due to the application of the pressure of the body against the body-contacting surface of the interlabial device.

Another approach to achieve a desirable topsheet with the appropriate physical properties can include hi-loft webs manufactured in either an airlaid process or a carded process. For example a suitable web can be manufactured by airlaying a relatively low basis weight (<30gsm) of staple fibers (approximately 8mm long) containing a modest level (approximately <25%) bi-component binding fiber and thermally bonding the fiber web without calendaring. For example a fiber blend of 40% PET (Celanese #295 polyester fibers, 8mm length, obtained from Celanese AG (Summit, NJ, USA)), 40% Lyocel (1.25 denier, 8mm available from Tencel Inc. Mobile, AL) and 20% bi-component fiber (8 mm, 1.2 denier, C1.7 dtex, FiberVisions AL Adhesion United States). layed down to a basis weight of 20 gsm without calendaring. Ideally these fibers are of a relatively low denier (<2 denier) to improve the webs apparent softness. Alternatively, a calendaring process (using longer fibers of the same fibers disclosed above) can be used

to lay down such a web followed by a thermal bonding step using through air bonding to effectively point bond individual fibers within the web.

ABSORBENT CORE

5 The absorbent core 44, which is best seen in FIG. 2, is positioned between the topsheet 42 and the backsheet 38. The absorbent core 44 provides the means for absorbing exudates such as menses and other body fluids. The absorbent core 44 preferably is generally compressible, conformable, and non-irritating to the user's skin. The absorbent core 44 can be of any suitable size and shape. Preferably, the absorbent
10 core 44 has the same general shape as the overall absorbent interlabial device 20.

 The absorbent core 44 may comprise any suitable material that is capable of absorbing and/or retaining liquids (e.g. menses and/or urine). The absorbent core 44 can be manufactured from a wide variety of liquid-absorbent materials commonly used in absorbent articles such as comminuted wood pulp which is generally referred to as airlaid.
15 Examples of other suitable absorbent materials include cotton fibers or cotton lintels, creped cellulose wadding; meltblown polymers including conform; chemically stiffened, modified or cross-linked cellulosic fibers; synthetic fibers such as crimped polyester fibers; peat moss; tissue including tissue wraps and tissue laminates; absorbent foams; absorbent sponges; superabsorbent polymers (in fibrous and particulate form); absorbent
20 gelling materials; or any equivalent material or combinations of materials, or mixtures of these. Preferred absorbent materials comprise folded tissues, cotton batts, woven materials, nonwoven webs, rayon including needle punched rayon, and thin layers of foam. The absorbent core 44 may comprise a single material or a combination of materials.

25 One preferred material for the absorbent core 44 is a batt of rayon or a rayon/cotton blend. In one embodiment, the absorbent core 44 is a batt of fibers which comprises a 50%/50% blend of baled bleached cotton fibers and baled rayon fibers. A tri-

lobal rayon known as GALAXY rayon available from Acordis of Mobile, Alabama USA has been found to work well for the material comprising the absorbent core 44.

5 The storage core 44 can comprise fibrous superabsorbent material in any suitable amount. Some non-limiting preferred ranges for the amount of fibrous superabsorbent material include between: about 25% to about 100%; about 25% to about 70%; and about 25% to about 50% by weight. Any ranges included within these ranges are also included. The higher concentrations of superabsorbent material specified about (e.g., above 70%), are particularly suitable if the storage core 44 comprises a relatively open high loft nonwoven material. This high loft nonwoven material could, for example, be a carded nonwoven. Alternatively, instead of comprising fibrous superabsorbent material, in less preferred embodiments, the superabsorbent material can be in the form of particles, or any other form known in the art. In other embodiments, the storage core 44 can comprise superabsorbent material in a combination of different forms.

10 The storage core 44 can comprise of a high capacity, high concentration (of fibrous AGM) airlaid storage core. Airlaid process, superabsorbent fiber, bi-component fiber, and airfelt process produce a high capacity, high concentration (of fibrous AGM) airlaid storage core. The airlaid comprises a basis weight of a range of about 75 - 500 g/m². The preferred range for a basis weight is 100 - 400 g/m². The most preferred range is from 150 - 350 g/m². The composition of the airlaid is between 20% and 100 % fibrous AGM. The preferred composition of fibrous AGM is between 30 to 70% fibrous AGM. The most preferred composition of fibrous AGM is between 35 to 60%. The Bi-Component fiber is between 3 % and 12 %. The preferred range for the Bi-Component fiber is between 4% to 8%. The most preferred range is from 4% to 6%. The remaining composition is airfelt. The density is less than 0.2 g/ccm. The density of the airlaid is preferably less than 0.16 g/ccm and most preferably between 0.10 and 0.14 g/ccm when measured under 7.0 g/sqcm (0.1 psi) pressure.

The Super absorbent fiber (SAF) fiber length ranges from 6mm to 12 mm and preferably 8mm. The super absorbent fiber denier ranges from 10 to 30 denier. The fiber

capacity free swell greater than 30g/g, preferably greater than 40; and the most preferred greater than 50g/g in bovine blood. The super absorbent fiber retention is at 0.5 psi greater than 20g/g, preferably greater than 30 g/g; and most preferred greater than 40g/g in bovine blood.

- 5 The Bi-Component fiber length is 3mm to 6 mm, preferably 4mm. The bi-component C1.7 dtex, 4mm fiber denier is less than 3 denier, preferably less than 2 denier obtained from FiberVisions AL Adhesion located in the United States.

- The airfelt comprises standard 100% kraft cellulose fibers obtained from Korsnas A-E located in AB Sweden. Additionally a blend of standard kraft cellulose and a stiffer, i.e.
10 Eucalypt fiber to keep the airlaid more open is also appropriate.

- One non-limiting material suitable for use as the storage core 44 in the integrated acquisition layer/storage core structure described above comprises about 45% FIBERDRI type 1162 superabsorbent fibers obtained from Camelot Technologies Ltd. of Alberta Canada; about 49% airfelt fluff obtained from Korsnas A-E (Sweden); and about 5-6%
15 of 4 mm long C1.7 dtex bicomponent fiber (AL Adhesion) comprising a polypropylene core with a polyethylene sheath obtained from FiberVision of Covington, GA, USA.

- One preferred non-limiting material suitable for use as the storage core 44 is a 300 g/m² airlaid composed of SAF, airfelt, BiCo; 50 % Super absorbent FiberDry type 1162 fiber obtained from Camelot Technologies Ltd. in Alberta Canada; 45 % Airfelt fluff
20 obtained from Korsnas A-E; and 5 % BiCo C1.25 dtex, 4mm obtained from FiberVisions AL Adhesion located in the United States. The storage core is manufactured on a M & J pilot airlaid line with two forming heads (Netherlands).

- Another preferred non-limiting material suitable for use as the storage core 44 is a 200 g/m² airlaid composed of SAF, airfelt, BiCo; 50 % FiberDry type 1162 super
25 absorbent fiber obtained from Camelot Technologies Ltd. Alberta Canada; 45 % Airfelt fluff obtained from Korsnas A-E; and 5 % C1.7 dtex, 4mm BiCo obtained from

FiberVisions Adhesion. The storage core is manufactured on a M & J pilot airlaid line with two forming heads which is located in the Netherlands.

The storage core 44 can comprise any suitable structure that is capable of efficiently storing the body discharges that are received from the acquisition layer 46. In one preferred embodiment, the storage core 44 comprises a 300 g/m² airlaid layer comprised of superabsorbent fibers, airfelt, and bicomponent fibers. Although the superabsorbent fibers can be distributed in any suitable manner within the storage core, the superabsorbent fibers are preferably distributed substantially uniformly throughout the storage core 44. The storage core 44 is preferably comprised of a high concentration (greater than or equal to about 25% by weight) of a fibrous superabsorbent material (or absorbent gelling material), preferably a high gel strength fibrous superabsorbent material.

Traditionally, such a high concentration of superabsorbent material (particularly fibrous superabsorbent material) would not be expected to deliver efficient core performance due to gel blocking. However, as shown in Figure 13, using a needle punching technique (such a technique is used to make plush piled carpets, for example) the acquisition layer 46 can be vertically integrated directly into the storage core 44 (fibers from the acquisition layer in the needle punching process are driven through the storage core and anchored below). Without wishing to be bound to any particular theory, this technique ensures efficient fluid transfer from the acquisition layer 46 to the storage core 44 without flooding the superabsorbent material while the needle punched nonwoven fibers from the acquisition layer 46 actually help to keep open the storage core 44; both aspects working to avoid gel blocking.

FIG. 13 shows another preferred absorbent core structure. FIG. 12 shows the relationship of the portion of the absorbent core structure shown in FIG. 13 to the overall interlabial device. The absorbent structure shown in FIG. 13 is especially preferred when improved fluid handling is desired. The absorbent structure comprises a novel structure comprising an acquisition layer 46 and an absorbent core, or "storage core" 44, in which

the acquisition layer 46 is integrated or "placed into communication" with the storage core 44 by needle punching. The term "placed into communication" with encompasses configurations in which an element is directly secured to another element by affixing the element directly to the other element; configurations in which the element is indirectly
5 secured to the other element by affixing the element to intermediate member(s) which in turn are affixed to the other element; and configurations in which one element is integral with the another element, i.e., one element is essentially part of the other element.

In other alternative embodiments, FIG. 25 the acquisition layer 46 in the absorbent core could be omitted altogether.

Figure 13 shows that the absorbent core 44 is needle-punched. Needle punching is a method of mechanically interlocking fiber webs by physically repositioning some of the fibers as fiber tufts or bundles from a horizontal to a vertical orientation. The repositioning means is a barbed needle and fiber repositioning is achieved by penetrating the needle into the web in a manner that permits the barbs to carry groups of fibers from
10 one layer to form a fiber plug and withdrawing the needle in a manner that permits the fibers to remain in their new position. Needles should be less than about 40 gauge. Preferably, the needles should be in the range of 25 gauge. A relatively simple needle choice and set-up is chosen with the intent of primarily integrating the acquisition layer onto the storage core and re-orienting the acquisition layer fibers into the vertical plane
15 without significant densification of the acquisition layer. Needling density is determined by the distance advanced and the number of penetrations per stroke.

Most needled fabric is made in flat form; however, tubular fabric, ranging in diameter from a few millimeters to papermakers-felt dimensions, can be made on specially designed machines. Fabric weights range from about 50 g/m² to 5000 g/m² at
25 needling densities ranging from fewer than a hundred to several thousand penetrations per square centimeter. Needles for needle punch machinery are produced by Foster Needle, Groz-Beckert, Singer, and others.

In a preferred non-limiting version of needle-punching the density of penetrations is greater than about 10 penetrations per square cm, more preferably greater than about 25 penetrations per square cm and more preferably still greater than about 50 penetrations per square cm.

5 In a preferred non-limiting version of needle-punching, needle punching is performed with a needling density of 100 needles per square inch; fiber lengths for carding and needling were approximately 1.5 inch (38mm). Needle punched samples were supplied by Texel Inc. (Quebec, Canada).

10 As shown in Figure 19, the most common needleloom configuration is the single upperboard, downstroke arrangement. Other arrangements include double upper-board, single upper-and lower-board, and double upper-and lower-board. To achieve high penetration densities on both sides of a fabric, needlelooms of various configurations are placed in tandem.

15 Needlelooms are produced in widths ranging from several centimeters to several meters. Each manufacturer offers a range of machine designs differing basically in width, arrangement, and number of needleboards and other parameters. Virtually all needlelooms employ reciprocating motion to provide the penetration action.

20 The process converts the web of loose fibers into a coherent nonwoven fabric using a needle loom. Needle looms of various type are well known in the art and function by bonding a nonwoven web by mechanically orienting fibers through the web. The needle loom can be operated to produce patterned or unpatterned products.

25 Needlelooms with low-density boards are used to lightly consolidate webs and are termed pre-needlers or needletackers. Machines with multiple or high-density needle capabilities are often referred to as consolidation or finisher needlelooms. Machines designed to produce patterned or raised surfaces are termed structuring looms and are used as a mechanical finishing process or for special effects.

By varying the strokes per minute, the number of needles per loom, the advance rate of the batt, the degree of penetration of the needles, and the weight of the batt, a wide range of fabric densities can be made.

5 The degree of interlocking is dependent primarily on the extent to which the needle penetrates the web (depth of penetration), the needling density (penetrations per unit area of fabric), and the number of groups of fibers repositioned per penetration (needle design).

10 The preferred embodiment has a hole distribution consisting of a random hole arrangement with each hole separated from an adjacent hole (in any direction) by a distance of between 1-2 mm.

15 Fig. 19 shows the basic elements of a needlepunch machine 231. The basic elements of the needlepunch machine are: a web feeding mechanism 225; a needle beam 226; a needleboard with needles 227 preferably consisting of up to 150 needles/square inch, more preferably 75 to 100 needles/square inch; a stripper plate 228; a bed plate 229; and a fabric takeup mechanism. The fiber web 230 (sometimes carried or reinforced by a scrim or other fabric) is guided between the metal bed and stripper plates, which have openings corresponding to the arrangement of needles in the needleboard. The fiber web 230 width preferably has a width of 50 cm.

20 During the downstroke of the needle beam, each barb carries groups of fibers, corresponding in number to the number of needles and number of barbs (up to 36 barbs) per needle, into subsequent web layers a distance corresponding to the penetration depth. During the upstroke of the needle beam, the fibers are released from the barbs and interlocking is established. At the end of the upstroke, the fabric is advanced by the take-up and the cycle is repeated. The line advancement rate is chosen according to 3 criteria:

25 i.) The acquisition layer fiber orientation is altered from a predominantly horizontal to vertical orientation; ii.) the acquisition layer is firmly anchored into the storage core without significant densification of the layer; and iii.) the overall structural integrity of the airlaid storage core layer is not degraded.

As shown in FIG. 13, the needle punching process causes a plurality of vertical channels 48 to be formed in the storage core 44. There is also a portion 49 of the acquisition layer 46 that underlies the storage core 44 as a result of the needle punching process. The needle punching process may pull the acquisition layer 46 in the z direction which may result in the portion of the acquisition layer 49 underlying the storage core. The portion 49 of the acquisition layer can but does not have to be the same material from the acquisition layer 46.

In another alternative embodiments, the topsheet 42 in the absorbent core could be omitted altogether. In this particular embodiment, the absorbent core 44 which has a fuzzy layer is needle-punched.

Similarly, in another alternative embodiment, the acquisition layer 46 in the absorbent core could be omitted. In this particular embodiment, the absorbent core is needle punched.

Fig. 32 is a graph comparing the interlabial device's core capacity with needle-punching versus without needle-punching. The test method used to assess the respective core capacities is commonly referred to as a demand absorbency test (DAT) or a horizontal gravitational wicking test (HGW) as disclosed in the application of Richards, et al PCT WO 95/10996. In this method a core sample size of 26sqcm is selected. The core capacity in the HGW test can be measured using either an artificial menstrual blood solution as disclosed in PCT WO 95/10966 or a synthetic urine solution. An appropriate synthetic urine solution is disclosed in the application of Bewick-Sonntag et al PCT WO 97/24096. In Fig.32 the value of the core capacity per gram of absorbent material is a measure of the test liquid that remains within the core following the "initial uptake" in the HGW test and a subsequent application of a 70g/sqcm (1 psi) squeezing pressure to remove free liquid from within the core. For this application of pressure the core is squeezed between whatman filter paper stacks for a 30 second interval.

In addition to needle-punching other techniques to integrate the fibers from the acquisition layer to the storage core may also be used such as forced air flow, forced air

jets to drive fibers from the acquisition layer into the storage core or even high pressure water jets (for example, hydro entangling techniques). In the description given above the storage core is shown to be composed of two discrete manufacturing steps; the formation of an airlaid core structure with a high percent of fibrous AGM and the step of
5 manufacturing a carded nonwoven web that is then needle punched into the airlaid structure. Typically this core would be manufactured in two separate locations using diverse manufacturing techniques that are not generally available at the one manufacturing site. An approach to simplify this making operation is foreseen by combining both manufacturing steps at the airlaid point of manufacture. Namely using a
10 multiple head airlaid system it is possible to airlay both a storage core layer using for example the first two airlaying heads as detailed above and then to airlay an appropriate acquisition layer on top of this storage core using either one or more additional airlaying heads. Integration of these layers is still possible using a more simplified needling approach such as that achieved via a spiked calendaring role configuration. In such a
15 configuration the spiked calendaring rolls serve the purpose of both delivering the core to its desired thickness and driving, at regular intervals, fibers from the acquisition layer into the storage layer for more efficient fluid transport between these layers. With the correct fiber choice this acquisition layer may be sufficiently comfortable also to act as a viable topsheet layer to interface with bodily tissues while the product is being worn and
20 eliminate an additional topsheet requirement.

SLITS

As shown in Figures 20 - 22, three executions have been conceived to achieve superior contact of an interlabial pad to the inner labial surfaces for improved fit
25 performance. As shown in Figure 20, the first approach is to apply multiple, closely spaced slits in the absorbent core. As shown in Figure 21, the second approach is to apply preferred folding lines 227. As shown in Figure 22, the third approach is to actually divide the core up 44 into multiple sections 228 (via cutting the core into sections) so that each section has the potential to move independently.

In a preferred embodiment, the method comprises a combination of slitting in both machine direction (MD) and/or the cross machine direction (CD). The term "machine directions" as used herein refers to the direction of travel of the forming surface onto which fibers are deposited during formation of an absorbent nonwoven web. The term
5 "cross-machine" direction as used herein refers to the direction which is perpendicular to the machine direction defined above.

The first approach is when the absorbent interlabial device 20 be constructed with a plurality of slits 232 in the main absorbent portion 22 so as to permit bending of the product in multiple directions. Such a structure allows the product to more easily respond
10 to the stresses associated with body movements and to better adapt to the wide range of labial vault structures. The simplest approach is to apply multiple, closely spaced slits 232 predominantly in CD direction into the core to allow each core zone to act and move relatively independently so as to conform to the unique surface structure present at that point. Another approach is to apply multiple, closely spaced slits 301 predominantly in
15 the MD into the core to allow each core zone to act and move relatively independently so as to conform to the unique surface structure present at that point. An additional approach is to apply multiple, closely spaced slits in both the MD 301 and the CD 232 into the core to allow each core zone to act and move relatively independently so as to conform to the unique surface at that point.

20 The slitting of the core can be performed in either one or two steps. In a typical two step operation we slit the cores in machine direction as part of the needle punching set up off line. This produces a unidirectional (MD) slitted core that maintains a high degree of integrity and residual MD tensile strength so that it can still be readily handled on a high speed converting line. The second step can be performed on our converting line by
25 applying a second slitting operation in the cross machine direction to complete the slitting operation. Alternatively a complex bi-directional slitting operation can be performed in one step on line as part of the overall product manufacturing procedure. In such a set up the slits would still be bi-directional, as detailed above but offset about 5 degrees from the production lines center line to facilitate superior slitting and knife lifetimes.

In the MD slitting set up, each slit is between 5.0 mm and 10 mm long, preferably about 7.0 mm long and separated by about at least 5 mm from the next slit in MD. Each MD row of slits is separated by about at least 5.0 mm and preferably less than 10.0 mm to the next adjacent row. In the CD slitting set up, each slit is between 5.0 mm and 10 mm long, preferably about 7.0 mm long and separated by about at least 5.0 mm from the next slit in CD. Each CD row of slits is separated by about at least 5.0 mm and preferably less than 10.0 mm to the next adjacent row.

Other slitting configuration are also feasible and may involve simple straight lines or just unidirectional slitting or complex shapes and directions. In addition, slitting can occur in just the MD or the CD. Alternatively, at its most extreme each core element may not be substantially attached to adjacent core elements, such that each core element (or particle/piece) is able to flow into and fill each available space within the labial vestibule.

The absorbent interlabial device 20 needle punched core technology provides an excellent starting point for improving core adaptability both macroscopically and microscopically. In the first step of core making we produce the needle punched core that is relatively stiff and features a high degree of core integrity. This core in its present form does not adapt well to a wide range of labial vestibule shapes and sizes. Through a simple slitting technique the core adaptability can be significantly increased so that it is better able to flow into the shape required to match the available anatomy. Since the core starts with a high degree of integrity slitting tends to convert the core into a multitude of semi individual elements that are able to adapt in each dimension while each element nevertheless maintains a high degree of integrity that is required for maximization of fluid handling.

A second approach, as shown in Figure 21, is to apply preferred folding lines 233. A third approach, as shown in Figure 22, is to actually divide the core up 44 into multiple sections 234 (via cutting the core into sections) so that each section has the potential to move independently.

A fourth approach uses absorbent particles (or beads) that are enclosed within an interlabial bag such that the bag and absorbent material is able to adapt to any shape or contour that the women may have. This option represents the greatest degree of

adaptability excluding the use of a liquid gel or fluid as an absorbent media. Particles can be a dimensions of greater than 100 microns.

In a preferred version of the embodiment shown in Figure 18, the top surface of the structure may have one or more slits or have other regions of preferred bending so that product may easily adjust to vertical pressure against the pelvic floor, to help accommodate the non-linear surface of the pelvic floor between the clitoris and the perineum.

A series of examples have been developed to demonstrate the key aspects of the interlabial product. The following examples will provide detail on the product's materials

10 :

Example 1:

The product dimensions are 91mm x 46 mm and 5.0 mm caliper.

The product is composed of the following materials;

- 15 • A starch bonded rayon topsheet of about 15g g/m² similar to that used as an overwrap for tampons (in particular TAMPAX tampons) and supplied by BBA Nonwovens of Green Bay, Wisconsin.
- The core material is a carded batt of a 50/50 blend of rayon and cotton blend. A 50% Sarille L rayon fiber is combined with a 50% blend of cotton combers with a 0.03% leomin finish and supplied by Brannoc of North Devon, England.
- 20 • The backsheets is a Polybutylene succinate adipate film colored with Ampacet 110361 available as BIONELLE 3001 and obtained from Showa High Polymer Co. of Tokyo, Japan. The backsheets is attached to the topsheet to form a perimeter seal via a crimping operation.
- The core is attached to the backsheets with the aid of two spiral hot melt adhesive bonds centrally positioned either side of the integral keel construction (so as to provide a 20mm wide glue free zone in the product center) and of a dimension of 40mm long, 8mm wide.

25

- The keel design is referred to as an integral keel design and is detailed in the application WO PCT 99/56689. Due to its design and lack of any structural integrity this keel design does not facilitate a controlled and reproducible product insertion/application technique. On the other hand it is highly flexible and thus does not contribute to product discomfort while wearing.

Example 2

The product dimensions are 91mm x 46 mm and 6.0 mm caliper.

The product is composed of the following materials;

- A thermally bonded nonwoven of 17gsm basis weight manufactured by Vliesstoffwerke Christian Heinrich Sandler GmbH & Co.KG (Schwarzenbach/Saale, Germany) under the tradename Sawabond 4313. The topsheet has been mechanically modified to improve comfort as detailed and claimed in the U.S. Application Serial number. 09/637,440 filed on Aug.11, 2000.
- The absorbent core structure is composed of a 60gsm nonwoven acquisition layer (Texel Inc., Quebec/Canada) composed of 50% PET (Celenese #295 from Celenese AG (Summit, NJ/USA) and 50% Rayon/CMC Alloy fiber (Accordis, Mobile, Alabama/USA under the trial code 2014) joined, through needle punching operation, to a 300gsm absorbent airlaid core composed of a homogeneous blend of 42% airfelt (Korsanas A-E, Sweden), fibrous AGM (Fiberdry 1162 (Camelot, Alberta/Canada) and 8% bicomponent fiber (AL Adhesion C1.7 dtex, from Fibervisions Covington, GA/USA). The needle punching was performed by Texel Inc. (Quebec/Canada) and core material supplied to Procter & Gamble (Cincinnati, OH/USA) under the code Texel 04354.5.
- The core flexibility has been enhanced through the application of parallel lines (separated by 5mm gaps) of slits orientated in the machine direction (parallel to product length) each 10mm long and separated by a 5 mm to the next slit. The slits run from the top to the bottom of the core structure and completely slit the material through its depth.

- The backsheet is a Polybutylene succinate adipate film colored with Ampacet 110361 available as BIONELLE 3001 and obtained Showa High Polymer Co. of Tokyo, Japan. The backsheet is attached to the topsheet to form a perimeter seal via a crimping operation.
- The core is attached to the backsheet with the aid of two spiral hot melt adhesive bonds centrally positioned either side of the centrally placed (externally applied) keel construction (so as to provide a 20mm wide glue free zone in the product center) and of a dimension of 40mm long, 8mm wide.
- The keel design chosen for this example is a simple externally applied keel design as shown in Figure 3. It is attached to the backsheet in an inward orientation and over a distance of 27mm length and 4 mm width (area of contact with the backsheet is 108 sqmm). The length of the keel that can be grasped (protruding above the backsheet) is 27 mm long mm and it protrudes to a height of 13 mm above the backsheet. The graspable area is 310 sqmm (slight tapering on the ends). The material utilized for this laminated keel construction is composed of an 80 gsm multi-bonded airlaid supplied by Buckeye Technologies (Memphis, TN/USA) and a 23gsm nonwoven supplied by BBA (Piene, Germany) under the trade name Corolind (PE HPC-2). Due to its simple construction design and the flexibility of the chosen materials this keel design does not facilitate a controlled and reproducible product insertion/application technique. On the other hand it is highly flexible and thus does not contribute to product discomfort while wearing.

Example 3:

The product dimensions are 91mm x 46 mm and 6.0 mm caliper and is composed of identical materials and an identical keel design to that of example 2. The overall product flexibility and ability to conform to the labial vestibule structure has been enhanced through an alternative core slitting design to that chosen in example 2. All else remains the same except;

- The core flexibility and ability to conform to the labial vestibule has been further enhanced through the application of parallel lines (separated by 5mm gaps) of slits

orientated in the cross machine direction (transverse to product length) each 10mm long and separated by a 5 mm to the next slit. The slits run from the top to the bottom of the core structure and completely slit the material through its depth. This alternative slitting pattern reduces the force required to bend the product in the V-bend and L-bend test and thus facilitates a deeper insertion/application of the product within the labial vestibule.

Example 4:

The product dimensions are 91 mm x 46 mm and 6.0 mm caliper and is composed of identical materials to that of example 2. However the product has been further improved in its flexibility, its ability to conform to a wider range of vulva vestibule shapes and a superior keel design for insertion control has been utilized. All else remains the same except;

- The core flexibility and ability to conform to a wider range of labial vestibule shapes and sizes has been further enhanced through the application of slits orientated in both the machine direction (along the product centerline) and the cross machine direction (transverse to product length). Each slit (in each direction) is 6.5 mm long and separated by a gap of 5 mm to the next slit. The slits run from the top to the bottom of the core structure and completely slit the material through its depth. This alternative slitting pattern allows a greater decoupling of each core element from neighboring elements and allows a much improved 3-dimensional conformity to the labial surface structure. It allows this without an increase in the force required to bend the product in the V-bend and L-bend test versus example 2 while facilitating an even deeper insertion/application of the product within the labial vestibule.
- The keel design chosen for this example is a externally applied keel design as shown in Figure 3. It is attached to the backsheet in an outward orientation and over a distance of 27mm length and 11 mm width (area of contact with the backsheet is ~380 sqmm with minor edge rounding). The length of the keel that can be grasped (protruding above the backsheet) is 27 mm long mm and it

protrudes to a height of 20 mm above the backsheet. The graspable area is 500 sqmm (slight tapering on the ends). The material utilized for this laminated keel construction is composed of an 80 gsm multi-bonded airlaid supplied by Buckeye Technologies (Memphis, TN/USA) with a 23gsm nonwoven supplied by BBA (Piene, Germany) under the trade name Corolind (PE HPC-2) laminated on both sides of the airlaid. Due to its reinforced construction design this keel design facilitate a highly controlled and reproducible product insertion/application deep within the labial vestibule. However, due to its size (both attached to the backsheet (270sqmm) and protruding over the backsheet (500sqmm) and the relative stiffness of the materials utilized to make the keel construction this keel can be uncomfortable (due to too deep insertion and keel stiffness, excessive dimensions) for some users of the product. This stiffness is apparent in the higher value of the result for this example in the keel stiffness test method.

Example 5:

The product dimensions are 91mm x 46 mm and 6.0 mm caliper and is composed of identical materials to that of example 2. In addition, the core flexibility improvements detailed in example 4 have also been applied exactly for this example. For this example we only modified the keel design versus the design chosen in example 4. All else remains the same except;

- The keel design chosen for this example is a externally applied keel design as shown in Figure 3. It is attached to the backsheet in an outward orientation and over a distance of 20 mm length and 11 mm width (area of contact with the backsheet is ~220 sqmm with minor edge rounding). The length of the keel that can be grasped (protruding above the backsheet) is 27 mm long mm and it protrudes to a height of 20 mm above the backsheet. The graspable area is ~440 sqmm (tapering design narrower where keel is attached to backsheet). The material utilized for this laminated keel construction is composed of an 80 gsm multi-bonded airlaid supplied by Buckeye Technologies (Memphis, TN/USA) with a 23gsm nonwoven supplied by BBA (Piene, Germany) under the trade name

Corolind (PE HPC-2) laminated only on one side of the airlaid (as used in example 2-3). Due to the higher area of attachment of the keel to the backsheet (versus example 2-3) and superior graspable area this keel design facilitate a controlled and reproducible product insertion/application deep within the labial vestibule without being noticeably uncomfortable versus keel designs used in example 2-3. The keel stiffness for this example greater than that for example 2-3 giving superior insertion control but not as stiff as in example 4 that drove comfort negatives for some of the product users. See the data in the keel stiffness method results.

As shown in Figure 23, examples 1 - 5 listed in the data table have been evaluated either for their ability to control soiling when used as a menstrual product or their level of comfort when worn for menstrual use.

Evaluating a products soiling performance in use is particularly useful when evaluating products that are to be worn predominantly within the labia due to the complexity of how products are loaded and where these products are worn on the body. A standard in-use soiling evaluation protocol has been developed to assess products soiling performance when worn by women during menstruating.

The standard in-use soiling protocol has a key steps. A group of at least 20 women are selected who regularly use menstrual products such as pads or tampons. We exclude women of very low flow or women of excessive flow. The women are given five test products and five products as a control product. The women use the products in an alternating manner and after wearing the products both the product and the underwear that were worn with the product are carefully packaged and immediately returned to a laboratory for detailed assessment of product soiling and to assess for the presence of soiling on the under garments. The protocol can be run with highly experienced users (used this product for at least 5 consecutive periods) of this product if one wishes to assess how soiling is influenced by the selection of materials such as the absorbent core or topsheet. In such a protocol Example 1 acting as a control product has been assessed against Example 2 that features the improved core technology detailed in this application.

On test completion the amount of soiling as a function of the amount of load for each example has been determined from the returned products. Considering all products with loads up to 2 grams, the control product, Example 1, has 70 % of these products soiled onto the underwear while being used. Whereas, Example 2, featuring the improved needle punched core technology has only 40 % of these products soiled onto the underwear while being used.

The level of soiling that women experience while wearing such a product is also dependent on their level of experience and familiarity with such a product. Inexperienced users tend not to insert the product to the optimal depth within their labial vestibule. This can occur through concerns of placing the product too deep or due to discomfort experienced during the application of the product. To assess the comfort and soiling performance of improved fitting designs we perform an in-use soiling study as detailed above but in this case select women who are not overly experienced (used this product form a maximum of two times in previous periods) with this product form. This provides a more sensitive testing protocol for product design changes involving fit. In such a protocol Example 3 acting as a control product (it has an improved slitting design compared to example 2 that starts to improve both product fit and comfort in-use) has been assessed against Example 4 that features the improved slitting and keel design to improve fit in-use. On test completion the amount of soiling as a function of the amount of load for each example has been determined from the returned products. Considering all products with loads up to 2 grams, Example 3, has 27 % of these products soiled onto the underwear while being used. Whereas, Example 4, featuring the improved core fitting and product application technology has only 17 % of these products soiled onto the underwear while being used. In this testing Example 3 was considered more comfortable to wear than Example 4 whose attached keel was stiffened and extended in length. Example 5 has a further improved attached keel to further improve the wearing comfort in-use.

In a more preferred version, the amount of non-biodegradable bicomponent fiber is further reduced to about 4% to enhance the overall ability of the storage core to disintegrate and degrade. The storage core should achieve at least a level of "product

disintegration" greater than 35% in the 28 day sludge test method after 28 days. More preferred is a level of "product disintegration" in excess of 70% in the 28 day sludge test method after 28 days. Even more preferred is a value in excess of 95% after 28 days and most preferred is a value in excess of 90% already after 7 days in this test The core disclosed in Example 5, achieves a level of disintegration of 90% after just 7 days and a level of 95% after 28 days.

Alternatively, the storage core 44 can comprise biodegradable bicomponent fibers to aid in the biodegradability of the product, or alternatively a water soluble latex binder such as an EVA based latex binder type Airflex192 available from Air Products Inc. (Allentown, PA, USA) can be used to impart integrity to the airlaid storage core 44 while delivering superior biodegradability. Another approach to enhance the cores biodegradability while minimizing the use of binders is to utilize the natural adhesion properties of fibrous AGM's in a wet environment to bind the core and achieve the desired core integrity. This can be achieved, for example during an airlaid process, by passing the fiber stream, as it exits the forming heads, through a nebula water spray zone so that the fibrous AGM on absorbing part of this moisture during its transport through the moisture zone becomes sticky and discrete point bonds bind neighbouring fibers into a cohesive core structure. Excess moisture is removed as the web passes through a conventional oven typically found on such lines. In one non-limiting embodiment, the storage core 44 can be manufactured on an standard thermally bonded airlaid line with two or more forming heads, which creates an integrated multi-layered structure.

ACQUISITION LAYER

The acquisition layer 46 can comprise any suitable structure that is capable of quickly taking in body fluids. Suitable types of acquisition layers are described generally in U.S. Patent 5,591,149 issued to Cree, et al. on January 7, 1997. In one preferred embodiment, the acquisition layer 46 comprises a high loft nonwoven web that has a fuzzy appearance. The meaning of the term "high loft" is known to those of skill in the art who deal with nonwoven materials. This fuzzy layer is designed to have a high z-direction (downward) wicking capability that is better able to contact the vaginal discharges through the

apertures in the topsheet, including such discharges as blood that may be trapped or wicking within the labial membrane folds, and deliver these discharges downward to a high suction storage core 44.

One non-limiting material suitable for use as the acquisition layer 46 has a basis weight of about 30 - 140 g/m². In a preferred version of this embodiment the acquisition layer has a basis weight of about 50 - 80 g/m². The most preferred version has a basis weight of about 60 g/m². The composition is highly varied and is based on the end product application in flushable products which contain biodegradable fibers such as rayon, polyactic acids, etc. The acquisition layer 46 caliper prior to needling is less than 4 mm, preferably less than 3 mm most preferable less than 2.5 mm when measured under 7.0 g/sqcm (0.1 psi) pressure. The acquisition layer 46 caliper after needling is less than 3 mm, preferably less than 2 mm most preferable less than 1.5 mm when measured under 7.0 g/sqcm (0.1 psi) pressure. The density of the acquisition layer 46 is less than 0.1 g/ccm, preferably less than 0.07 g/ccm most preferably less than 0.05 g/ccm when measured under 7.0 g/sqcm (0.1 psi) pressure. The fiber in the acquisition layer 46 is preferably less than 6 denier more preferably less than 4 denier. The fiber can be a blend of 2 or more fiber types and deniers. The fiber length is typical of carded processes, less than 100 mm and preferably in the 35-100 mm lengths.

One non-limiting material suitable for use as the acquisition layer 46 is a 60 g/m² carded nonwoven layer comprised of a mixture of polyethylene terephthalate (PET, a polyester) fibers and polypropylene fibers. In a preferred version of this embodiment, the acquisition layer 46 comprises about 75% by weight Celanese #295 polyester fibers obtained from Celanese AG (Summit, NJ, USA) and about 25% by weight FiberVision #163024 polypropylene fibers obtained from Fiber Visions (Covington, GA, USA).

Another non-limiting material suitable for use as the acquisition layer 46 is a 60 g/m² carded nonwoven layer comprised of a mixture of hydrophilic and hydrophobically treated rayon to ensure efficient wicking of bodily discharges and their transport to the storage core 44 without the rayon competing with the storage core 44 to serve the

function of storing the discharges. The acquisition layer 46 is comprised of 40% hydrophilic conventional tri-lobal GALAXY rayon of a 3 denier fiber containing 0.01% LEOMIN finish (known in Europe as "ASLAN") finish (a hydrophobic finish, which usually serves as a processing aid) and 60% hydrophobically-treated conventional tri-
5 lobal GALAXY rayon of a 3 denier fiber containing 0.3% LEOMIN (ASLAN) finish, both fibers supplied by Acordis (Mobile, AL, USA).

In a preferred non-limiting version of this embodiment, the acquisition layer comprises about 40% by weight of 40% hydrophilic conventional trilobal GALAXY rayon of a 3 denier fiber containing 0.01% LEOMIN finish supplied by Acordis (Mobile,
10 AL, USA) and about 60% by weight of BIONELLE 3001 biodegradable fibers obtained from Showa Hugh Polymer Co. of Tokyo, Japan or fibers that provide equivalent performance to the biodegradable fibers. The acquisition layer 46 can be manufactured and then physically combined to the storage core 44 through a needle punching process by Texel, Inc. of Quebec, Canada.

15 In a preferred non-limiting version of this embodiment, the acquisition layer comprises about 60 g/m² carded then needled nonwoven layer composed of a biodegradable PET and Rayon; 50 % biodegradable Polyester fiber (tbc); 50 % Acordis type 2014 Rayon. Textel Inc. in Quebec, Canada manufactures these materials by needle punching of the acquisition layer to the storage core.

20 One non-limiting material suitable for use as the acquisition layer 46 is a 60 g/m² carded nonwoven layer comprised of a mixture of polyethylene teraphthalate (PET, a polyester) fibers and polypropylene fibers. In a preferred version of this embodiment, the acquisition layer 46 comprises about 75% by weight Celanese #295 polyester fibers obtained from Celanese AG (Summit, NJ, USA) and about 25% by weight FiberVision
25 #163024 polypropylene fibers obtained from Fiber Visions (Covington, GA, USA).

In other embodiments, the absorbent core 44 may consist of multiple independent layers of the same, or different materials (such as layers of absorbent materials with

different absorbent properties), that are easily separatable so the various layers can separate for disposal.

In an alternative embodiment, instead of providing the topsheet 42 with the comfort enhancing properties described herein, the topsheet 42 could be a very open material, or a very thin material, and the underlying layer, such as the acquisition layer 46 (or the absorbent core 44) could be provided with the comfort-enhancing properties of the topsheet 42 described above. Such a topsheet 42 could serve primarily to retain fibers in the underlying acquisition layer 46 or core 44. In other words, an article can be provided in which the top surface structure comprises a first component (like the topsheet 42) having apertures therein and a second component (such as the acquisition layer 46) that underlies this first component. The second component can have portions that underlie the apertures in the first component, and portions of the second component that underlie the apertures in the first component can form part of the top or body-contacting surface of the article. In other alternative embodiments, the topsheet could be omitted altogether, and the body-contacting layer could be the acquisition layer 46, or the absorbent core 44, and the acquisition layer 46 or the absorbent core 44 could be provided with the properties described herein for the topsheet (for improving the comfort of the same).

BACKSHEET

The backsheet 38, which is best shown in FIGS. 2 and 3, prevents the exudates absorbed and contained in the absorbent core 44 from wetting articles and/or body parts which may contact the absorbent interlabial device 20 such as pants, pajamas, undergarments, pubic hair, the wearer's thighs, etc. The backsheet 38 should be flexible and impervious to liquids (e.g., menses and/or urine). As used herein, the term "flexible" refers to materials which are compliant and will readily conform to the general shape and contours of the human body. The backsheet 38 also provides protection for the wearer's fingers as the absorbent interlabial device 20 is inserted, or as the device is optionally removed with the fingers.

The backsheet 38 may comprise a woven or nonwoven material, polymeric films such as thermoplastic films of polyethylene or polypropylene, composite materials such as a film-coated nonwoven material, or organic material such as a collagen film. Other suitable materials include dispersible materials such as polyvinyl alcohol, and biodegradable polymers that can be made into films and the like. Suitable biodegradable polymers include: BIONELLE 3001 obtained from Showa Hugh Polymer Co. of Tokyo, Japan; BAK 403 biodegradable polymer obtained from Bayer AG of Leverkusen, Germany; Matter Bi ZF03U-A obtained from Bicorp Co., distributor for Novamont S.P.A. of Rome, Italy; and, Biopol biodegradable polymer obtained from Monsanto. In one embodiment, the backsheet may be made from a polyethylene film having a thickness of from about 0.012 mm (0.5 mil) to about 0.051 mm (2.0 mils). An exemplary polyethylene film is manufactured by Clopay Corporation of Cincinnati, Ohio, under the designation P18-0401. Preferably, however, the backsheet 38 comprises a film having a similar thickness to this polyethylene film, only which is made of a biodegradable polymer such as the BIONELLE biodegradable polymer described above.

The backsheet 38 may also permit vapors to escape from the interlabial device 20 (i.e., be breathable) while still preventing exudates from passing through the backsheet. A suitable breathable backsheet material is a laminate of an apertured film such as that described in U.S. Patent 3,929,135 issued to Thompson which is inverted so that the smaller openings of the tapered capillaries face the absorbent core 44 which is adhesively laminated to a microporous film such as that described in Exxon's U.S. Patent 4,777,073.

In preferred embodiments, the backsheet 38 is dispersible and/or dissolvable in water. Polyvinyl alcohol (including co-polymers of polyvinyl alcohol) has been found to be suitable as a material for a dissolvable backsheet 38. The polyvinyl alcohol may be coated on a tissue, a nonwoven material such as a biodegradable nonwoven material (e.g. rayon), or coated with a wax, such as paraffin, or other hydrophobic coating to reduce the rate at which it dissolves in water. This allows the backsheet 38 to maintain its integrity

during use, while retaining the ability to dissolve in water during disposal of the interlabial device 20.

In preferred embodiments, the backsheet 38 is dispersible and/or dissolvable in water. The term "dispersible", as applied herein to an absorbent interlabial device or a component thereof, refers to an article or material which will disperse into at least two fragments in mildly agitated water. Such a device will break into pieces in a conventional toilet and/or domestic plumbing system, and will ultimately be effectively processed through a sewage treatment system. The term "dissolvable", as applied herein to an absorbent interlabial device or a component thereof, refers to an article or material which will at least partially dissolve and essentially assume liquid form or otherwise be indistinguishable to the naked eye from the liquid medium in which it is dissolved.

In other embodiments, the backsheet can be eliminated. In some embodiments, the backsheet can be eliminated if the underside of the absorbent core is coated, or otherwise treated, to make the backsheet resistant to the passage of liquids therethrough. Alternatively, when the interlabial device 20 is folded along a longitudinal axis A (as shown in FIG. 4), especially if the device is primarily contained within the labia, the underside of the two halves of the interlabial device 20 which would normally be provided with a backsheet, will contact each other (that is, after the user's fingers are removed), and the main body portion of the device 20 will assume an inverted V or U-shaped cross-sectional structure. In this case, the portion of the device 20 which would normally be provided with a backsheet will not contact a wearer's garments, so the backsheet will not be necessary. The elimination of a backsheet will improve the breathability of the device.

The components of the absorbent interlabial device 20 described above (topsheet 42, backsheet 38, if one is present, acquisition layer 46, if present, and absorbent core 44) can be assembled in any suitable manner. The components may or may not be needle punched. In the embodiment shown in FIGS. 1-3, the components of the main body portion 22 are assembled in a "sandwich" configuration with the components sized so that

the edges of the topsheet 42 and backsheet 38 extend outward beyond the edges of the absorbent core 44.

5 The components of the interlabial device 20 can be joined together in any suitable manner. The term "joined," as used herein, encompasses configurations in which an element is directly secured to another element by affixing the element directly to the other element; configurations in which the element is indirectly secured to the other element by affixing the element to intermediate member(s) which in turn are affixed to the other element; and configurations in which one element is integral with the another element, i.e., one element is essentially part of the other element.

10 In the embodiment shown in FIGS. 1-3, the topsheet 42 and backsheet 38 are preferably at least partially peripherally joined using known techniques. As shown in FIGS. 1 and 2, the topsheet 42 is preferably secured to backsheet 38 along a seam 60. Seam 60 is preferably liquid impervious. The seam 60 can be formed by any means commonly used in the art for this purpose such as by gluing, crimping, or heat-sealing.

15 The seam 60 and the area of the interlabial device 20 in the vicinity of the seam 60 should be soft, compressible, and conformable. If the seam 60 and surrounding area are too stiff or non-compressible, the wearer may experience discomfort when wearing the interlabial device 20.

In addition to the peripheral seam, the components of the absorbent interlabial device 20 can be joined together at their faces. The faces of the components of the interlabial device 20 can be joined together by adhesives, stitching, heat and/or pressure bonds, dynamic mechanical bonds, ultrasonic bonds, intermingling or entanglement of the fibers or other structural elements comprising the components of the absorbent interlabial device 20, such as by meltblowing the fibers comprising one component onto another component, extruding one component onto another, or by any other means known in the art. The components of the absorbent interlabial device 20 may be joined with water soluble adhesives in order to increase the tendency of the device 20 to disperse into a plurality of fragments in mildly agitated water (such as in a toilet). It is, therefore,

desirable that the material joining the components lose strength when exposed to an excess of water, such as when placed in a toilet. Water soluble or water dispersible adhesives, such as those based on carboxymethyl cellulose, polyvinyl alcohols, starches, and the like are well known in the art.

5 INSERTION MEANS FOR THE INTERLABIAL DEVICE

As previously discussed, the absorbent interlabial device 20 is designed to be placed within the interlabial space of a wearer. As shown in FIG. 4, to use the absorbent interlabial device 20, the wearer grasps the tab 52 of the device 20. If the device 20 is not provided with a tab 52, the wearer may hold the folded device 20 at the sides 32 and
10 begin insertion. As shown in FIG. 4, the device 20 is then further inserted by pushing with a finger or fingers in the recess 62 formed by the folded backsheet 38. Recess 62 covers the tips of the wearer's fingers during insertion. This feature provides for a hygienic insertion of the absorbent interlabial device 20 of the present invention. The wearer may assume a squatting position during insertion to assist in spreading the labial
15 surfaces.

FIG. 5 shows the absorbent interlabial device 20 inserted into the interlabial space of a wearer W. The urogenital members shown in FIG. 5 include the bladder B, the vagina V, the urethra U, the clitoris C, the large intestine I, the anus AN, the vaginal introitus VI, the hymeneal ring H, the labia minora N, and the labia majora J. FIG. 5
20 shows the relationship of these anatomical features of the wearer W to the absorbent interlabial device 20 when the device is properly inserted for use. Once the absorbent interlabial device 20 is inserted, the topsheet 42 tends to remain in contact with the inside surfaces of the labia. When the wearer is standing, the labial walls close more tightly around the folded absorbent interlabial device 20.

25 Given the wide variety of labial sizes, shapes and membrane texture it is extremely difficult to design a limited number of IL-pad sizes that are able to fit correctly on a wide range of women. To solve this problem requires a new development, namely to design an adaptable, shape adjusting IL base pad that is able to alter its shape in use to

match the particular contours of each particular women's vulva vault. This development needs to be combined with a robust insertion device or design (either applicator, keel or insertion tabs) since the more flexible or adaptable the base IL pad is made the more difficult it is to insert/apply the IL pad within the labia.

5

Two executions have been conceived to achieve a consistent and deeper fit for a product worn interlabially. First, a reinforced tab 52 that provides integrity to the flexible pad so that the product can be pushed deeply into the labial vault achieving close proximity to the vaginal opening without bunching or twisting. As the tab 52 may cause
10 discomfort from the addition of stiffer materials, a folding line/crease may be added to the tab 52 so that once inserted it folds without interfering with wearing awareness. Second, an external applicator that is slim so that it can be placed between the fold of the product and has a blunt end so that it allows the product to be applied up to vaginal opening but does not allow the product to be inserted into the vagina. The applicator contacts the
15 interlabial product at the center of the product on the backsheet.

The absorbent interlabial device 20 is preferably provided with an optional insertion and/or removal tab 52 joined to the underside 20B of the main body portion 22. The tab 52 may be of any suitable size which provides for a convenient finger grip during insertion and, optionally, removal of the device 20. In the embodiment shown in FIGS. 1-
20 3, the tab 52 is about 20 mm long, and about 13 mm in height (i.e. measured in the "z"-direction after attachment). The tab 52 provides an element for the wearer to grasp the device 20 during insertion. The absorbent interlabial device 20 is designed to be expelled by urination. The tab 52, however, may provide an alternative mechanism for removal of the device 20 (i.e. removal with the fingers).

25

An enhanced insertion aide is used to facilitate application and fit of the product within the labial vault. This feature improves the application and fit of the product so that a flexible/adaptable product can be placed deep within the labial vault. As the depth of the product placement improves with the application device, the by-pass soiling will be

reduced. The interlabial base pad is thus improved by more contact with the vaginal opening.

The tab 52 may be made of a variety of materials and need not be absorbent. In one example, the tab 52 may be formed from a nonwoven material which is heat bonded to a tissue layer. A suitable nonwoven material is known as COROLIND and is available from BBA Nonwovens, Peine, Germany, the same material used for the topsheet prior to mechanically altering the same. A suitable airlaid tissue is available from Merfin Hygienic Products, Ltd., of Delta, British Columbia, Canada, having a basis weight of about 61 g/m² and having the designation grade number 176.

OTHER ASPECTS OF THE INTERLABIAL DEVICE

Preferably, the interlabial absorbent device 20 of the present invention is toilet-disposable. The term "toilet-disposable", as used herein, means that the interlabial device is capable of being disposed of in a toilet. The interlabial device is preferably at least flushable. In particularly preferred embodiments, the interlabial device may also be provided with one or more of the following characteristics: dispersibility, settleability, disintegrateability, and biodegradability.

As used herein, the terms "flushable" and "flushability" refer to a product's ability to pass through typically commercially available household toilets and plumbing drainage systems without causing clogging or similar problems that can be directly associated with the physical structure of the product. It is recognized, however, that there can be many differences between the various types of toilets available. Therefore, for the purposes of the appended claims, a test to determine the flushability of a catamenial product, such as an absorbent interlabial device, is set out in the Test Methods section of this specification.

Preferably, the absorbent interlabial device 20 of the present invention is dispersible and will disperse into at least two fragments within two hours of exposure to mildly agitated room temperature water as described in the Water Dispersion Test in the Test Methods section, below. More preferably, the interlabial absorbent device 20 will be

dispersed into a plurality of fragments within about 60 minutes or, even more preferably within about 30 minutes, and most preferably, within about 15 minutes as measured by the Water Dispersion Test. Preferably, the product will break into fragments which individual fragments are smaller than about 6 in², more preferably smaller than about 4 in², most preferably smaller than about 2 in². In particularly preferred embodiments of the present invention, each of the components of the interlabial absorbent device 20 will disperse into a plurality of fragments when immersed in mildly agitated water. Alternatively, the components of the absorbent interlabial device 20 may separate from each other without themselves breaking into a plurality of fragments (e.g. the topsheet 42, backsheet 38, and core 44 may break apart from each other while each otherwise remaining intact).

"Settleability" refers to the tendency of an absorbent interlabial device, such as absorbent interlabial device 20 to eventually settle to the bottom of a septic tank or other sewage treatment system rather than to float on the surface of such tanks or sewage being processed.

Disintegrateability and biodegradability can be measured in accordance with the 28 Day Sludge Test which is contained in the Test Methods section of this specification. Preferably, the absorbent interlabial device 20 comprises biodegradable materials. While biodegradable materials are preferred for the absorbent interlabial device 20, it is not necessary that each and every material used be biodegradable. For example, the device 20 may comprise superabsorbent particles which do not biodegrade, and this will not affect the ability of the overall device 20 to remain toilet-disposable and to be effectively processed in a sewage treatment system. On an overall weight basis, the interlabial device 20 is preferably at least about 70% biodegradable, more preferably at least about 80% biodegradable, more preferably still at least about 90% biodegradable, and most preferably, at least about 95% biodegradable.

The absorbent interlabial device 20 as shown in its fully assembled configuration, preferably comprises at least one axis of preferred bending A. The axis of preferred

bending A is preferably located generally along the longitudinal centerline L of the absorbent interlabial device 20. The axis of preferred bending A is a line or axis along which the absorbent interlabial device 20 will tend to bend or fold when subjected to compressive forces F directed inwardly in the transverse direction at the sides 32 of the device 20. The axis of preferred bending A may result naturally from the product configuration, or the device 20 may be imparted with a weakened axis or region in any or all of the topsheet 42, backsheet 38 and core 44 to create the axis of preferred bending A. Such a weakened axis may be created by any variety of known techniques such as scoring, pre-folding, slitting, or the like. The absorbent interlabial device 20 may comprise a region of preferred bending made up of a plurality of axes of preferred bending. Any number of such axes may comprise such a region of preferred bending up to an infinite number.

The absorbent interlabial device 20 is folded along the axis of preferred bending A, as shown in FIG. 4, prior to insertion within the wearer's interlabial space. Once inserted, the device 20 will preferably tend to unfold slightly keeping the topsheet 42 of the device 20 in contact with the inner walls of the wearer's labia. The device 20 may be resiliently biased slightly along the axis of preferred bending A to increase the tendency of the device 20 to unfold. This allows the folded device 20 to act as a "spring" under both wet and dry conditions and, consequently, to increase the tendency of the topsheet 42 of the device to remain in contact with the inner surfaces of the labia when the absorbent interlabial device 20 is in place. A device 20 constructed according to the preferred embodiment described above, however, does not necessarily require any additional structural features to provide the ability to maintain such contact.

The absorbent interlabial device 20 described herein is preferably both flexible and compressible. Flexibility and compressibility are important to product comfort. If the absorbent interlabial device 20 is too flexible, the device is not conveniently or easily placed between the folds of the labia, if it is too stiff, the device is uncomfortable and

when the user is in a sitting position, the product can be forced forward against the clitoris causing discomfort.

5 The absorbent interlabial device 20 shown in FIGS. 1-3 (i.e. one in which the device is tapered at the ends) allows the device to easily and comfortably fit the wearer's interlabial space. A device 20 with such a tapered shape, when folded along an axis of preferred bending A (as in FIG. 4) will have a profile in which highest point along the axis of bending A (as measured in the "z"-direction) is in the vicinity of the center of the device 20 rather than at the ends. The folded configuration of the device 20 when properly sized as described above allows for consistent coverage of the walls of the labia and the vaginal introitus. Such coverage substantially reduces the incidence of "by-pass" around the device 20 by menstrual or other bodily discharges which are exhibited by previous interlabial pads.

15 The configuration of the absorbent interlabial device 20 is also responsible for improved product performance. As described above, there is a reduced likelihood of body or clothing soiling from discharges which are absorbed by the device 20. Additionally, when the device 20 is folded along the axis of preferred bending A, the interlabial device 20 will form a recess 62 which protects the wearer's fingers from soiling when the device 20 is inserted.

20 The absorbent interlabial device 20 (with or without a backsheet) may also be worn in combination with the absorbent article, such as a sanitary napkin or a pantiliner. In such a case, the absorbent interlabial device 20 will keep the sanitary napkin or pantiliner cleaner, allowing the wearer to wear the sanitary napkin or pantiliner longer than usual.

25 Previous interlabial pads have not provided the attributes of the device 20 shown and described herein, and are thus not able to obtain the performance and comfort results described herein. Several previous pads consisted of a small generally cylindrically shaped absorbent material which is inserted into the interlabial space. These devices are

characterized by a less clean insertion and removal and may be associated with increased panty and body soiling in comparison to the present device 20.

Other previous pads were much larger than the device 20 described herein and included significant portions which resided externally to the interlabial space. Such designs may also lead to increased body soiling as discharged bodily fluids migrate to the external surfaces of such pads. Additionally, the interlabial device 20 described herein is believed to offer comfort advantages (e.g. reduced wearing awareness) as compared to the above-described larger prior art pads. These and other interlabial devices were not sufficiently flexible, and did not simultaneously cover both labia when the wearer moved in certain manners (e.g. when the wearer squatted), and therefore, such devices did not conform to and spread with the labia. This resulted in less efficient collection of bodily exudates. Still other interlabial devices were folded and retained in a folded configuration. This would prevent such devices from opening and closing to conform to the labia when the wearer moved.

The absorbent interlabial device 20 also better conforms to the labial vault than previously available interlabial pads. Additionally, the generally flat and folded configuration of the absorbent interlabial device 20 described herein is found to give a better visual indication to users as to how to insert and use the device. Therefore, the absorbent interlabial device 20 is associated with an easier and more accurate insertion as compared to previous interlabial pads.

Other embodiments of the interlabial device 20 are also possible. Non-limiting examples of other suitable configurations for the interlabial device are contained in U.S. Patent 5,762,644 entitled "Toilet-Disposable Absorbent Interlabial Device", which issued to Osborn, et al. on June 9, 1998, the disclosure of which is incorporated by reference herein. The interlabial devices described in this patent may comprise a central absorbent portion and a pair of flexible extensions joined to the central absorbent portion. The flexible extensions preferably extend downwardly and laterally outward from the upper

portion of the main absorbent portion, and are preferably capable of maintaining contact with the inside surfaces of the wearer's labia majora.

The interlabial device 20 is preferably at least partially retained in place by exerting a slight laterally outwardly-oriented pressure on the inner surfaces of the wearer's labia minora, labia majora, or both. Additionally, the product may also be held in place, to a degree, by attraction of naturally moist labial surfaces to the material comprising the topsheet 42. Optionally, the interlabial device 20, or any suitable portion thereof, such as at least one body-contacting surface of the interlabial device, can have a substance thereon to assist the interlabial device in staying in place in the desired position in the interlabial space. Preferably, the substance should comfortably maintain the interlabial device 20 in contact with the inside surfaces of the labia minora, or alternatively with the inner surface of the labia majora, or with both the labia minora and labia majora so that it remains in contact with these surfaces (on both sides of the interlabial space) unaided by the wearer's panties, or the like, when the wearer moves in a way that the labia spread (e.g., when the wearer is squatting with her feet about shoulder width apart). The topsheet can be adhered by the substance to portions of the wearer's body tissues, but top surface still has to maintain ability to stretch/adjust for motions and movements of the wearer's body. This will allow the interlabial device 20 to remain in place during wearing conditions, and will also ensure that it is contacted by a stream of urine when the wearer urinates so that it will be removed on urination or be easily dislodged by a wiping action such as with toilet paper.

Typically, the unloaded interlabial device 20 will weigh less than or equal to about 5 grams. The need for a substance to assist the interlabial device in staying in place becomes more important as the loading that the interlabial device 20 is expected to hold (that is, the weight of absorbed bodily liquids) increases. The absorbent interlabial device 20 can hold any suitable amount of bodily liquids up to its absorbent capacity specified above. As the weight of absorbed bodily liquids increases, the force of gravity on the loaded interlabial device increases. This results in the need for increased ability to hold

the interlabial device 20 in place, particularly when the exudate loading is greater than or equal to about 8 grams (e.g. 8, 10, 12, or 15 grams). Thus, for example, if the unloaded interlabial device 20 weighs 2 grams, and is expected to hold 10 grams of bodily exudates, the interlabial device 20 must stay in place under a force of 12 grams. Also, in
5 some instances as the interlabial device 20 becomes loaded, if it is of a configuration which has flexible extensions, one of the flexible extensions may separate from the labia adjacent thereto while the other flexible extension remains adhered to the adjacent labia. This leads to an increased risk of soiling the wearer's undergarments and/or outer garments at heavier loadings because of the possibility that bodily exudates could travel
10 past the side of the interlabial device that is no longer in contact with the wearer's labia.

The substance used for holding the interlabial device 20 in place should have sufficient strength for holding the device securely in place, particularly against the naturally moist surfaces of the interlabial portion of the wearer's body. It should also be a material that allows the interlabial device 20 to be capable of removal without pain or
15 trauma to the user. Preferably, the substance for holding the interlabial device 20 in place holds the device in place under the desired loadings as described above, but permits the interlabial device to be expelled from the interlabial space into the toilet when the wearer urinates. The substance, therefore, need not be adhered so that is capable of withstanding fluid pressures from the urethra of greater than or equal to about 100 centimeters of water.
20 That is, it need only be able to withstand a pressure that is between the weight of the device when loaded up to a pressure of less than about 100 centimeters of water. (A pressure of 170 centimeters of water is the approximate maximum bear-down pressure for a typical adult human female when urinating.)

The substance for holding the interlabial device 20 in place preferably has certain
25 additional characteristics. It should allow the interlabial device 20 to be easily placed in the proper position without discomfort, and worn without irritation. It should also preferably be biodegradable so that it is suitable for disposal in a toilet. The presence of the substance should also not interfere with the flushability of the interlabial device, if the

interlabial device is of a flushable design. Preferred substances for holding the interlabial device in place are those which provide resistance to detachment under shear forces (such as those acting when the wearer walks), but can be comfortably removed using peeling forces.

5 The substance for holding the interlabial device 20 in place can include materials which are typically identified as adhesives, as well as materials which are not generally considered adhesives (that is, non-adhesive substances). Suitable adhesives include pressure sensitive adhesives and tacky non-pressure sensitive adhesive substances. Suitable pressure sensitive adhesives include silicone-based pressure sensitive adhesives
10 such as polysiloxane, modified polysiloxanes, hydrocolloid-based adhesives, starch-based adhesives, and moisture-activated adhesives.

Optionally, the interlabial device is provided with a non-adhesive substance on its body-contacting surface to hold the interlabial device in place. The non-adhesive substance can be of a type that has a "tack" (that is, stickiness), or it can be of a type that
15 does not have a "tack". Suitable non-adhesive substances include waxes (such as microcrystalline waxes, paraffinic waxes, silicone waxes, polyethylene waxes), fatty alcohols, high molecular weight alcohols, fatty acids, petroleum jelly, sealing ointments, non-ionic surfactants such as ethoxylated alcohols, ethoxylated long chain alcohols, and ethoxylated fatty acids, alkoxylated amide, alkoxylated amines, alkyl amido alkyl amines,
20 alkyl substituted amino acids, moisture-activated substances, and combinations thereof. Another suitable non-adhesive substance is the fat substitute OLEAN manufactured by the Procter & Gamble Company of Cincinnati, Ohio under U.S. Patent 5,085,884 issued February 4, 1992 and U.S. Patent 5,422,131 issued June 6, 1995, both to Young, et al. and U.S. Patent 5,422,131 issued to Elsen, et al. Without wishing to be bound by any
25 particular theory, it is believed that such materials may hold an object in place due to high viscosity or surface tension.

Moisture-activated substances are substances which have little or no initial tack (that is, they will be dry to the touch), but when contacted by moisture (preferably

relatively small amounts of moisture), they become viscous and develop a tack. Preferred moisture-activated materials for use in the present invention lose most of their tack when flooded with an excess of moisture such as when the wearer urinates. Moisture-activated substances are particularly preferred for use with the interlabial device 20 because they

5 can make the interlabial device easier to apply than pressure sensitive or tacky adhesive-coated devices because the product does not adhere to the body as it is inserted and because it is not necessary for the wearer to spread her labia and risk soiling her hands when placing the interlabial device as may be necessary when adhesives are used. In addition, moisture-activated substances will not tend to stick to the wrong portions of the

10 wearer's body when the product is placed between the labia and become mis-oriented, as will adhesives. They are also particularly useful for holding the interlabial device securely against this portion of the wearer's body since moisture is naturally present. In other words, they are capable of hydrating *in vivo*.

Some particularly preferred moisture-activated substances are polyethylene

15 glycols ("PEGs"), sodium carboxymethylcellulose (preferably USP (U.S. Pharmacopia) grade), alcohols, glycols (dihydric alcohols) such as propylene glycols, hexylene glycols, polyols which contain three or more hydroxyl groups, such as glycerin, and sugar alcohols and other molecules capable of hydrogen bonding by contact with the water in the interlabial region, surfactants such as polyoxyl alkylates (polyoxyethylene sterates),

20 ethoxylated alcohols, sugar surfactants, and sugars (such as glucose, fructose, and sucrose), or combinations or mixtures thereof. The foregoing substances may be used alone, in combination with each other, such as in combination with polyethylene glycols, or in combination with pectin, guar gum, locust bean gum, hydroxypropyl guar gum, polyglucomanum gum, cationic guar gum, anionic guar gum, alginate, xanthan gum, or

25 combinations or mixtures thereof, and combinations or mixtures thereof with polyhydric alcohols.

Polyethylene glycols ($\text{HO}-(\text{CH}_2 \text{ CH}_2 - \text{O})_n\text{-H}$), also abbreviated as PEG's, are substances like those found in cough syrups to coat a person's throat. Polyethylene

glycols are available from Union Carbide under the trademark CARBOXWAX. PEG 200 to PEG 600 (PEGs with molecular weights between 200 and 600) are liquid at or below 80° F (27° C). PEG 900 to PEG 20,000 and above are solid at or below 80° F (27° C). All are at least 60% soluble in water at 20° C. Preferably, the higher molecular weight PEG's which are in solid form are used. However, the lower molecular weight PEG's can also be used. Polyethylene glycols can be applied to the body-contacting surface of the interlabial device using any conventional processing steps, which are described in greater detail below. Once applied, they will typically dry to a non-tacky powder form. Polyethylene glycols, since they are water soluble, are also capable of losing their tendency to stick to the labia when the wearer urinates, so the interlabial device will be expelled by urination as intended. Their water solubility also ensures that they will not interfere with the ability of flushable interlabial devices to flush down a toilet, and will not float in the toilet as will some other products. (The tendency for other products to float reduces the ability of the products to go down the toilet when flushed and results in an extremely inconvenient situation for users who have to remove such products from the toilet bowl, and then dispose of these products.) Polyethylene glycols are also biodegradable, unlike most pressure sensitive adhesives, which are silicon-based.

One particularly preferred moisture-activated substance comprises a mixture of 1.75 g sodium carboxymethylcellulose, USP; 0.25 g polyethylene oxide, NF; and 125 ml distilled water. The mixture is preferably applied in a total amount of 0.15 g per each interlabial device (wet weight) if the mixture is only applied to the sides of the product, or in a total amount of 0.30 g per interlabial device if the mixture is to be applied to the entire body-contacting surface of the product.

The substance for holding the interlabial device in place can be combined with other substances before it is applied to the interlabial device. Such other substances can serve as a component of the substance for holding the interlabial device in place, or as a carrier for the substance for holding the interlabial device in place. Non-limiting examples of substances that can serve in either of these manners are lotions, emollients,

and mineral oil. For example, the substance for holding the interlabial device in place can be a polyethylene glycol that is mixed in a lotion formula that provides lubricity during the insertion process and develops tack when contacted by moisture. In another example, an emollient can be used as a carrier for PEG's which are in particulate form.

5 In still another example, the PEG's can be in liquid form, and can serve as a carrier for other materials. Such other materials may include, but are not limited to, spermicides.

The substances described above can be applied to the body-contacting surface of the interlabial product (or other type of device described herein) in an intermittent pattern, a continuous pattern, or in a pattern that has both continuous and intermittent portions.

- 10 Applying the substances in an intermittent pattern may be useful if it is desired to minimize interference of the substances with acquisition of liquids into the interlabial device 20 since liquids can be transported into the absorbent core between the intermittent zones of the substance. Applying the substances in a continuous pattern may be useful if it is desired to use the contact that the substance makes to the wearer's body
- 15 to create a barrier to the flow of exudates over the body-contacting surface of the interlabial device. However, the application of the substances in a continuous pattern should not form an impermeable barrier which prevents menses or urine from being absorbed by the interlabial device 20.

- The substance can be applied in any suitable manner, such as by spraying, padding,
- 20 use of transfer rolls, or by printing, such as by gravure or screen printing. The substance can be applied directly to the interlabial device, or it may be applied to another material or component which is then adhered to the desired portion of the interlabial device.

- The substance can be placed on any suitable portion of the interlabial device 20.
- 25 The substance can be placed on the entire body-contacting surface of the interlabial device 20, or on a portion thereof. For example, the substance can be placed on all or a portion of the body-contacting surface of the main body portion 22. If the interlabial device is of a type that comprises a central absorbent portion and flexible extensions extending therefrom, the substance can be placed on the central absorbent portion, the

flexible extensions, or both the central absorbent portion and the flexible extensions. The substance can, thus, be placed on a central region of the interlabial device 20, but not on the peripheral portions of the interlabial device. More preferably, however, the substance may be placed on the peripheral portions of the body-contacting surface of the interlabial device, but not in the central region. Locating the substance in the latter manner may be advantageous if it is desired to minimize any tendency for the substance to interfere with acquisition of bodily liquids into the interlabial device 20. The substance can also be used to create a seal to prevent the flow of exudates toward the ends (and/or sides) of the device. The substance can cover any of the following percentages of the surface area of the body-contacting surface of the main body portion 22, the central absorbent portion, the flexible extensions, or the entire body-contacting surface of the interlabial device (greater than or equal to about): 5%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, or 100%.

The substance can be applied to the interlabial device 20 in any suitable quantity. For these purposes, the quantity of the substance applied to the interlabial device 20 will be expressed in terms of the total product weight including the device and the weight of the substance. Preferably, the substance constitutes less than or equal to about 20%, more preferably less than or equal to about 10%, and most preferably less than or equal to about 5% of the total product weight, so as not to excessively contribute to the overall weight of the interlabial device. This permits more of the total product weight to be dedicated to providing absorbent capacity.

There are many possible specific embodiments of interlabial devices with various substances thereon for assisting the interlabial device in staying in place in the desired position in the interlabial space. The interlabial device can have one or more of the substances described herein applied thereto in any of the patterns of application described herein.

For example, the main body portion 22 of an interlabial device having the configuration shown in FIGS. 1-3, or the flexible extensions of an interlabial device

described in the patent incorporated by reference herein, may be provided with a biocompatible adhesive to assist the adhesion of that portion of the interlabial device to the inside surfaces of the wearer's labia. The strength of such an adhesive should be selected to assist the absorbent interlabial device 20 in staying in place, while still
5 allowing for reliable, and comfortable removal of the device from the wearer's interlabial space. Examples of suitable adhesives include hydrocolloids or hydrogel adhesives that are currently available in the market, and acrylic-based adhesives.

In other embodiments, any desirable combinations of the substances described herein, or combinations of patterns of application, or both may be used. One non-limiting
10 example would be to apply a combination of an adhesive and a non-adhesive substance to the interlabial device. For example, in the case of an interlabial device having the configuration described in U.S. Patent 5,762,644, issued to Osborn, et al., a polyethylene glycol can be provided on the body-contacting surface of the central absorbent portion, and a pressure sensitive adhesive can be provided on the flexible extensions. Preferably,
15 if adhesives are used, they are applied to portions of the interlabial device that do not block or retard the flow of urine from the urethra into the absorbent interlabial device 20.

In another example, the interlabial device 20 may be provided with one of the substances described herein (such as an adhesive) around the periphery of the body-contacting surface of the interlabial device to assist the device in staying in place adjacent
20 to the wearer's labia. The substance can be applied in a continuous or an intermittent pattern, or a pattern which is partially continuous and partially intermittent. A swelling absorbent material can be placed inside the area defined by the substance. If a complete seal with the wearer's body is desired, this swelling absorbent can be used to eliminate any gaps or void spaces that may occur adjacent to the wearer's body that may occur due
25 to misplacement of the interlabial device relative to the wearer's labia, and create a self-sealing device. Some non-limiting examples of swelling absorbent materials include, but are not limited to superabsorbent, hydrogel forming materials, absorbent foam materials,

modified cross-linked cellulosic fibers, and compressed absorbent materials, such as those used in tampons.

Fig. 14 shows an embodiment in which the topsheet 42 has a plurality of ridges and valleys therein. In the embodiment shown in Fig. 14, the substance for maintaining said topsheet 42 in contact with the wearer's body is located on at least some of said ridges on the body-contacting surface of the topsheet 42. The valleys, however, are preferably substantially devoid of the substance for maintaining the topsheet in contact with the wearer's body. The substance for holding the interlabial device in place is preferably only applied to ridges so that the portions of the topsheet having the substance thereon will be maintained in contact with the wearer's body, and the portions of the topsheet between the ridges will be extensible to conform to the movements of the wearer's body. As in the case of the other embodiments shown and described herein, this embodiment of the body-contacting topsheet can be used for any article that is to be placed in contact with a wearer's body, and is not limited to use on an interlabial device.

Numerous other embodiments and properties for the substance for holding the interlabial device in place are also possible. For example, the substances described herein preferably have moisture vapor transmission rates sufficient to maintain the natural state of hydration of the labial tissue. Suitable moisture vapor transmission rates are not less than about 300 gm m/hr at a relative humidity difference of 10 to 100%. In addition, any of the substances described herein can be used in conjunction with, or be combined with emollients such as those described in U.S. Patent 5,609,587 entitled "Diaper Having a Lotioned Topsheet Comprising a Liquid Polyol Polyester Emollient and an Immobilizing Agent", issued March 11, 1997 to Roe, and U.S. Patent 5,643,588 entitled "Diaper having a Lotioned Topsheet" issued on July 1, 1997 to Roe, et al.

In addition to the various embodiments of the substances for holding the interlabial device 20 in place which are described herein, the interlabial device can be provided with other optional features. For example, it has been found that the interlabial device of the present invention provides a substantial noticeable benefit to the user in controlling odors

associated with body exudates. Additional odor controlling agents may be added to seek further reductions in odors. Such odor controlling agents include, but are not limited to activated charcoals, zeolites, silica, polyacrylic acids (superabsorbents), certain quaternary compounds, triethyl citrate, cyclodextrin, or any combinations thereof.

5 Particularly preferred cyclodextrin compounds are described in U.S. Patent 5,429,628 issued to Trihn, et al. and U.S. Patent 5,780,020 issued to Peterson, et al. In addition, deodorants can be added to further mask these odors.

Further, over-the-counter vaginal drug actives can be added for one or more of the following purposes: cleansing, providing soothing and refreshing effects, deodorizing,

10 relieving minor irritation, reducing the number of pathogenic microorganisms, altering pH so as to encourage the growth of normal vaginal flora, producing an astringent effect, lowering surface tension, producing a mucolytic effect, or producing a proteolytic effect. Such over-the-counter vaginal drug actives include: calcium propionate, dioctyl sodium sulfosuccinate, nonoxynol 9, octoxynol 9, potassium sorbate, povidone-iodine (PVP-

15 iodine), sodium lauryl sulfate, and sodium propionate.

In these or other embodiments, the articles described herein, such as interlabial device 20, or any of the components thereof, can be made of extensible and/or stretchable materials to aid in the ability of the article to comfortably remain in place when forces are exerted on the article during wear. However, it is particularly desirable to form the

20 interlabial device or some portion thereof from extensible and/or stretchable materials when substances are applied to the interlabial device to assist the interlabial device in staying in place in the interlabial space. For example, if the interlabial device has portions that are adhered to the labia, some extensibility is preferably present for improved comfort and to reduce the possibility of irritation. Specifically, it is desirable

25 not to restrict the movement of the wearer's labia when the wearer's body moves. Suitable extensible materials that could be used for the components of the interlabial device, or other articles described herein, are described in U.S. Patent 5,611,790 entitled "Stretchable Absorbent Articles", which issued to Osborn, et al. on March 18, 1997.

The absorbent interlabial device 20 can be worn as a "stand alone" product. Additionally, superior performance in reducing body and clothing soiling over extended periods of wear time (such as overnight) can be obtained by using the absorbent interlabial device 20 as part of a "system" of feminine hygiene products. One such system which is effective in reducing soiling is an absorbent interlabial device, such as absorbent interlabial device 20, which is worn simultaneously with a sanitary napkin, such as sanitary napkin 70 (shown in FIG. 15).

Such a system of an interlabial device in combination with a sanitary napkin is more effective than either a sanitary napkin or an interlabial pad worn alone. The absorbent interlabial device used in such a system may, and preferably does, have all of the preferred attributes of the absorbent interlabial device 20 described above. The sanitary napkin 74 may be any suitable conventional sanitary napkin. The sanitary napkin 74 preferably comprises at least a liquid pervious topsheet 76, a liquid impervious backsheet 78 joined to said topsheet, and an absorbent core 80 positioned between the topsheet 76 and the backsheet 78. Additionally, the sanitary napkin 74 preferably includes a pressure sensitive adhesive 80 disposed on the garment facing side of the backsheet 74. The adhesive 84 allows the sanitary napkin 74 to be adhered to the crotch portion of the wearer's undergarments. When the undergarments are worn in their usual wearing position, the sanitary napkin 74 will rest adjacent the pudendal region of the wearer's body. The sanitary napkin 74 may also be provided with additional features commonly found in sanitary napkins, including "wings" or "flaps" such as wings 82. A suitable sanitary napkin for use in the above-described system is the "ALWAYS" Ultra thin Maxi with Wings sanitary napkin which is manufactured and packaged by the Procter & Gamble Company of Cincinnati, Ohio under one or more of U.S. Patents: B1 4,589,876; 4,687,478; 4,950,264; 5,009,653; 5,267,992; 5,354,400; 5,389,094; 5,489,283; 5,620,430; 5,704,930 and Re. 32,649. Other sanitary napkins are also acceptable, such as those without wings 78 and those which are not of the "Ultra-thin" type.

In order to use an absorbent interlabial device and a sanitary napkin as a system of feminine hygiene products, the wearer inserts the absorbent interlabial device into her interlabial space and places a sanitary napkin in the crotch portion of a panty-type undergarment. These two steps may be performed in either order. Some women will
5 prefer to place the sanitary napkin in the panty crotch first in order to catch and absorb and drops of menstrual flow which might be released prior to the time that the absorbent interlabial device can be inserted. Other women will chose to first insert the absorbent interlabial device. After the absorbent interlabial device is inserted and the sanitary napkin is positioned in the undergarment crotch, the undergarment is pulled up into its
10 usual wearing position. Consequently, the sanitary napkin will rests adjacent the pudendal region of the wearer's body and will be worn simultaneously with the absorbent interlabial device.

Preferably, the absorbent interlabial device used with the above-described system is changed each time the wearer urinates. The associated sanitary napkin may be worn
15 during for longer periods of time (i.e. beyond the changing of the absorbent interlabial device) because the bulk of the bodily fluids will be deposited on and absorbed by the interlabial device as opposed to the sanitary napkin. Particularly if the absorbent interlabial device 20 is provided with a tab 52 for removal, some women will prefer to remove the absorbent interlabial device 20 prior to urination, then subsequently re-insert
20 the same device 20 if it has not yet absorbed near its full capacity. In addition, if a woman chooses not to dispose of the interlabial device by flushing it down the toilet, the tab 52 provides a hygienic way for the woman to remove the product and dispose of it.

The sanitary napkin and the absorbent interlabial device of the above-described system may be packaged in a common package as a feminine hygiene "kit." Such a kit
25 facilitates use of the system of the present invention. Preferably, the packaging associated with such a kit will include instructions on how to use the absorbent interlabial device and the sanitary napkin according to the above-described method as a system of feminine hygiene products.

An alternate suitable system of feminine hygiene products comprises the absorbent interlabial device 20 used simultaneously with an absorbent tampon, such as tampon 86 shown in FIG. 16. The absorbent tampon of this system of feminine hygiene products may be any suitable conventional catamenial tampon including any of the tampons sold under the trademark "TAMPAX" and distributed by The Procter & Gamble Company of Cincinnati, Ohio. The tampon used may be either of the applicator insertion or digital insertion type and any suitable applicator known in the art may be used. The tampon is first inserted into the vaginal cavity of the wearer. Following insertion of the tampon, the absorbent interlabial device is inserted into the interlabial space of the wearer. The interlabial device and the tampon are then worn simultaneously for a period of time. The absorbent interlabial device may be removed and changed each time the wearer urinates, or may be removed then re-inserted subsequent to urination.

Similarly, the absorbent tampon and the absorbent interlabial device 20 of this system may also be packaged in a common package as a feminine hygiene kit. This kit facilitates use of the alternate system described herein.

Systems and associated kits of the present invention may also comprise the simultaneous use of an absorbent interlabial device, tampon, and sanitary napkin. Kits comprising all three types of feminine hygiene products may also be packaged in a common package and include appropriate instructions for use of such systems.

In addition, the present invention may also comprise a kit containing any combination of the following: oral contraceptive, injective contraceptive, hormone replacement therapy, interlabial device, tampon, and sanitary napkin.

In addition to the systems described above, the absorbent interlabial device 20 may be worn simultaneously with a pantiliner, or incontinence pad for menstrual or incontinence use. The absorbent interlabial device 20 described above may be combined and packaged with a pantiliner, an incontinence pad, or a sanitary napkin to form a feminine urinary incontinence kit. Such an incontinence kit preferably includes

appropriate packaging material instructing the wearer as to how to use the feminine hygiene products for light incontinence protection. The interlabial device 20 can be worn in conventional panties, or it can be used with menstrual shorts.

Furthermore, Numerous alternative embodiments of the absorbent interlabial device. For example, these products are designed to be removed by urination, although an alternative extraction string or loop may be used. These products may also be used with emollients and/or medicinal treatments. For example, a suitable emollient composition for use on the absorbent interlabial device 20 is comprised of about 50% petrolatum (such as White Protopet 1S made by Witco Corp.), about 35% Cetearyl Alcohol (a mixed linear C_{16} - C_{18} primary alcohol made by The Procter & Gamble Company under the name TA-1618), and about 15% Cetareth-10 made by BASF. An emollient coating of about 0.03 g/pad has been found to be suitable.

The absorbent interlabial device 20 may be provided with a visual indication on the center of the topsheet 42 designating the area of greatest absorbent capacity of the device 20. Such an indication may consist of a differently colored region such as a pink oval. The indication may be about 12 mm wide and about 20 mm long. The absorbent interlabial device 20 may also be provided with a visual change indication. In other words, the device 20 may have a ring, bonding pattern, compression lines, or other visual indicator provided on the surface of the topsheet 42 at a predetermined distance inboard from the seam 60. When absorbed bodily discharges reach the visual change indication or outboard of the change indication, the user knows to replace the absorbent interlabial device 20. Such a change indication is particularly useful to users who remove the device 20 prior to urination and then re-insert the same device 20 if it has not yet reached its absorbent capacity.

If desired, the absorbent interlabial device 20 may be packaged in an individual package. The individual package may be comprised of a number of suitable materials, including films and toilet-disposable materials. In one embodiment, the package can be made of a film which is frangibly sealed at the edges. The package can be provided with

an opening tab which can be of any suitable configuration. Suitable methods for frangibly sealing packages are described in U.S. Patent 4,556,146 issued to Swanson and U.S. Patent 5,462,166 issued to Minton, et al. Suitable tabs for such a package are described in U.S. Patent 5,413,568 issued to Roach, et al.

- 5 It should be understood that the substances and other features and components described herein may also be applied to other types of absorbent articles, including, but not limited to diapers, sanitary napkins, tampons, incontinence devices, pantliners, and bandages.

TEST METHODS

- 10 For all of the methods except the L Bend, V Bend, and Keel Stiffness Test, the standard laboratory climatic control as specified by TAPPI under T402 om-93, Section 3 (73°F or 23 °C \pm 1 °C, 50% \pm 2% RH) should be utilized. All samples should be acclimated to these conditions for at least two hours prior to measurements. The tests should be performed under similar conditions.

15 Material Critical Surface Tension

- For the purposes of the present invention, the hydrophilicity or hydrophobicity of a material is to be measured by determining the material's critical surface tension. Critical surface tension is determined by applying a series of liquids of known surface tension to a material and observing the wetting behavior. The critical surface tension of a material should be measured using the ASTM method for measuring the wetting tension of polymer films, ASTM D 2578-94. This method will work with nonwoven materials as well.

- 20 Examples of critical surface tension values for several materials of interest are as follows:

25	Material	Critical Surface Tension (dynes/cm)
	COROLIND	29-30
	BIONELLE	40

30

Topsheet Compressibility (Thickness Change)

This test procedure determines the topsheet caliper changes under pressures. This procedure can be used to calculate topsheet compressibility (and density) as a functions of two applied pressure loads. These pressures may be typical of those found within the labial vestibule while wearing an absorbent pad interlabially. However, this procedure is intended to be used to test topsheet materials whenever topsheet compressibility is specified in the appended claims, and is not limited to testing topsheets used only on interlabial products.

Sampling:

Samples should be cut such that they are larger than the 40 mm diameter circular foot that is used to compress the sample. A rectangular cutting die 10 cm by 10 cm was found to work well and to ensure no edge effects associated with irrecoverable sample compression during cutting occur. The area to be tested should be able to lie flat (preferably, less than 0.05 mm deviation in flatness). The structure of the topsheet should not, however, be altered in order to flatten the samples. Samples may be cut from a raw material roll or a finished product but the cut area must be free from wrinkles or curvature and must be representative of the undistorted dimensions of the topsheet material. The topsheet layer must be cleanly separable from other materials. At least three different samples should be measured with the average result reported.

For topsheet samples that are removed from a finished product and if the sample dimensions are not large enough to measure as described above, then a smaller diameter circular foot will need to be chosen. Provided that the applied pressure is maintained, as detailed below, and irregular edges or material damage linked to topsheet removal are avoided, the use of a smaller diameter circular foot is acceptable. If a smaller diameter foot is utilized, then a minimum of five samples should be measured to ensure a representative measurement of the topsheet surface is obtained. Ensure the topsheet is carefully removed without alteration of its surface structure.

Apparatus:

This testing procedure requires an accurate (to ± 0.01 mm) thickness gauge such as a Ono-Sokki GS-503 gauge available from Ono-Sokki Technology, Inc. of Addison, IL, USA equipped with an interchangeable circular foot. Ideally, the thickness gauge is attached to a digital readout module, such as a Ono-Sokki model DG-3610. To ensure no meaningful irregularities are present on the surface upon which samples are to be placed and measured, that would otherwise lead to measurement errors, a smoothly polished granite block (such as supplied by Rock of Ages Surface Plate, Barre, Vermont, USA polished to at least 0.001 mm flatness) or equivalent should be used as the measurement surface.

Circular measurement foot:

A circular flat foot of diameter = 40.0 mm \pm 0.5 mm and a weight of 10 g has been chosen.

Complete weight (foot + caliper shaft) = 32g \pm 1g.

15 Initial measurement pressure = 250 N/ m² (2.55 g/cm² or 0.036 psi)

Additional weight attached to shaft = 100 g \pm 1g

Final weight (foot + weight + shaft) = 132 g \pm 1g

Final measurement pressure = 1000 N/ m² (10.5 g/cm² or 0.149 psi)

Procedure:

- 20 1. Ensure the caliper gauge is calibrated using a standard gauge prior to commencing the measurements and accurate to ± 0.01 mm.
2. Place the sample with body facing surface facing upwards on the polished granite surface with the caliper shaft and foot assembly unit positioned centrally above the sample to be tested. The test is commenced with a standard circular foot (40 mm) and
- 25 a total shaft+foot weight of 32 g.

3. Gently lower the caliper shaft and foot assembly onto the sample and after waiting 5 seconds (but not more than 10 seconds) record initial sample thickness to the nearest 0.01 mm. This corresponds to the thickness under a pressure of 250 N/m^2 (2.55 g/cm^2 or 0.036 psi).
- 5 4. With the sample still positioned under the circular foot carefully place the additional weight disc (100 g) onto the caliper shaft (the total weight is now 132 g) and after waiting 5 seconds (but not more than 10 seconds) record the final sample thickness. This corresponds to the thickness under a pressure of 1000 N/m^2 (10.5 g/cm^2 or 0.149 psi).
- 10 5. The change in topsheet caliper is determined by subtracting the final caliper from the initial caliper (see calculation below).

Calculations:

- The change in topsheet caliper as a result of compressive forces is determined by;
- 15 $\text{Topsheet Caliper Change} = \text{Caliper (at } 250 \text{ N/m}^2) - \text{Caliper (} 1000 \text{ N/m}^2)$

- The greater the Topsheet Caliper Change number, the more the topsheet will be capable of compressing and adapting to compressive forces during during wear of the
- 20 absorbent device without directly passing these forces on to the sensitive membranes of the wearer's body.

Topsheet Low Force Extensibility Test

- 25 This test procedure determines the topsheet extensibility at low elongation force.

This procedure is based on ASTM methods D 5035-95 and D 117-97a. The determination of topsheet extensibility (as a function of % elongation) in cross-machine direction or machine direction is determined using these standard methods applied with the following specific details.

Sampling:

Representative samples should be cut from the topsheet material to a width of 25 mm (± 0.1 mm) wide and 100 mm long using an appropriate cutting die. These samples will be tested according to the ATSM D5035-95 definition "strip test". Strip samples may be cut from a raw material roll or a finished product, but the cut area must be free from wrinkles or curvature (e.g., from the raw material roll) and must be representative of the undistorted dimensions of the topsheet material. At least three different samples should be measured with the average result reported. Samples taken from products should be free from wrinkles, tears, holes or other defects, but the natural topography of the samples (e.g., corrugations and the like) should not be altered (e.g., by pulling them taut).

Apparatus:

An Instron model 5564 tensile tester available from Instron Corporation of Canton, MA, USA, or equivalent, is to be utilized for these tests. The Instron tensile tester is interfaced to a PC running WINDOWS 98 ® operating system and equipped with the data acquisition program MTS Test Works 4.0 TM software (capable of up to 400 Hz sampling rate) available from Sintech, Inc. of Research Triangle Park, N.C. USA. High speed data acquisition speed is critical for accurate measurements since the materials to be measured are potentially highly extensible at low applied forces. The instrument set-up parameters utilized to determine the topsheet extensibility (as % elongation at 50g load) are:

1. Sample clamp with 25 mm jaw.
2. Sample gauge length (separation of clamps at start of measurement) is 50 mm, or if a smaller size sample is used, the gauge length can be 25 mm.
3. Cross head speed is 50 mm/min.
4. A 10 Newton load cell is utilized.
5. Data acquisition rate is 400 Hz (400 data points/second).

Procedure:

1. Ensure the Instron or equivalent tensile tester is correctly calibrated according to the manufacturer's set-up and maintenance procedures prior to commencing the measurements.
2. Samples should be prepared according to the principles of ASTM 5035-95 and cut to 25 mm \pm 0.5 mm wide strips that are 100 mm \pm 10 mm long. Strips are obtained aligned both to the machine direction and cross direction of the topsheet material web. If samples are taken from products, several products will be needed, and one strip should be taken which is aligned with the length of the article to be tested, and one aligned with the width. If the sample is removed from a product, a smaller sample size will be acceptable provided it is at least of the dimensions 25 mm \pm 0.5 mm wide strips and 35 mm \pm 0.5 mm long. In this case, a gauge length of 25 mm will need to be selected.
3. Gently insert samples into the Instron's jaw clamps positioned to a gage of 50 mm. Ensure samples are correctly aligned vertically, parallel to the direction of elongation and centered, without wrinkles or twists, within the clamps. Ensure the starting force is recording at or close to zero force. If the value exceeds 1 g, reposition the samples within the sample holding clamps.
- Start the tensile tester to commence recording the force as a function of material elongation, the test is automatically terminated at the topsheet break point.

Measurements are recorded for topsheet extensibility in both the machine direction as well as the cross-machine direction.

4. The topsheet extensibility (expressed as % elongation at 50g force) is determined by a analysis of the recorded data as detailed (see calculation below).

Calculations:

The topsheet extensibility at 50 g force is determined from the data set. Given the high extensibility of these materials, it is critical to avoid irregularities associated with the sample set up at the test commencement. The sample should be minimally handled. It should be mounted in the clamp with no tension or a minimal (1 mm) amount of slack. To further minimize irregularities, all data points corresponding to a force less than 5 g are considered slack. At a load of 5 g, the gage gap is considered the zero point.

$$\% \text{ Topsheet Elongation (MD or CD)} = \frac{\text{Sample length (at 50g)} - \text{Slack length (at 5 g)}}{\text{Slack length (at 5g)}} \times 100\%$$

The greater this number, the more the topsheet is able to deform with the motions of the wearer's body without directly passing shear forces on to sensitive body membranes.

Surface Roughness

The surface characteristics (roughness, contact area of a topsheet as a function of depth/caliper) of a range of nonwoven and film topsheets can be assessed using a Zygo New View 200 scanning white light interferometer, (Zygo Corporation of Middlefield Connecticut, USA) set up according to the manufacturer's procedures as detailed in the user manual.

The following equipment set up parameters are used in these analyses: 2.5X Michelson objective with a zoom factor of 0.5X, the Zygo Focus white light filter element, normal resolution data acquisition (320x240 data points), Minimum Modulation % set equal to 1, and Minimum Area Size set equal to 7. The scan length was set from 800um to 1600um as appropriate for the topography of the samples.

The Frequency Domain Analysis was set to do calculations in Low mode.

Additionally, the data was processed using a 5 point average low pass filter to eliminate minor surface noise. To accommodate a larger field of view, a matrix of 4x5

(set up used for the SELFed COROLIND sample) and 3x4 (set up used for the Rayon) analyses were automatically stitched together using the Zygo MetroPro v7.3.2.3.1 software with a 10% overlap (final overall analysis area was 21.53 mm x 20.07 mm (SELFed COROLIND) or 16.29 mm x 16.15 mm (for rayon.)).

5 Estimates of surface contact area of each topsheet with another surface were calculated from the surface profiles at a series of depths (or calipers). To minimize the impact of high frequency surface noise on this analysis, the data was smoothed/ treated with an 11 point average low pass filter. A cylinder function was used to remove any slight global curvature of the sample due to the mounting procedure. The resulting surface
10 was analyzed by the MetroPro Bearing Plot routine. Using the Inspector tool of the Bearing Plot, the percent surface area exposed at a depth of 100 to 1000 microns from the first surface contact point was determined. This data was plotted (% Surface contact area versus sample profile depth, in microns).

15 Absorbent Capacity

Absorbent capacity may be determined as follows. The test is performed on samples that have been conditioned by leaving them in a room at 50% relative humidity and at 73°F for a period of two hours prior to the test. The test should be performed under similar conditions.

20 The article is weighed to the nearest 0.1 gram. The article is then submerged in a beaker of sterile 0.9% saline solution (obtainable from the Baxter Travenol Company of Deerfield, IL), such that the article is totally submerged and is not bent or otherwise twisted or folded. The article is submerged for 10 minutes. The article is removed from the saline and laid horizontally on a wire mesh screen having square openings 0.25 inches
25 by 0.25 inches (0.64 cm by 0.64 cm) for five minutes to allow the saline to drain out to the article. Both sides of the article are then covered with absorbent blotters, such as the filter paper #631 available from the Filtration Science Corp., Eaton-Dikeman Division of Mount Holly Springs, PA. A uniform 1 pound per square inch (6.9 Pa) load is placed over the article to squeeze excess fluid out. The absorbent blotters are replaced every 30
30 seconds until the amount of fluid transferred to the absorbent blotters is less than 0.5

grams in a 30 second period. Next, the article is weighed to the nearest 0.1 gram and the dry weight of the article is subtracted. The difference in grams is the absorbent capacity of the article.

5

Water Dispersion Test

Apparatus

Shaker Junior Orbit Shaker available from Lab Line Instruments of Melrose Park, Illinois.

Thermometer 30 to 120°F with 1 degree divisions

10 Timer Digital stopwatch

Jar with Lid 16 oz. glass jar with lid.

Test Setup

1. Fill the glass jar with 300 ml. of $73 \pm 3^\circ\text{F}$ tap water.
2. Set the speed on the Junior Orbit Shaker to 250 rpm according to the manufacturer's directions.

15

Procedure

1. Hold a sample (e.g. an absorbent interlabial device 20) 3 to 4 inches (7.6 to 10.2 centimeters) above the surface of the water in the jar. Gently drop the sample onto the water surface.
2. Place the lid on the jar.
3. Place the jar into the Junior Orbit Shaker such that the jar is oriented on its side.
4. Start the Junior Orbit shaker with the on/off switch, starting the timer when the shaker is turned on.

25

5. Record the time required until the sample separates into at least two pieces. Separation does not include the disassociation of a few individual fibers from an otherwise intact sample. The time is the total time the sample is being shaken.
- 5 6. Repeat steps 1 through 5 with three additional samples.

Calculation and Reporting

Calculate and report the mean and standard deviation of the water dispersibility time for the four samples tested.

Flushability Test

Overview

As noted above, the terms "flushable or flushability" refer to a product's capacity to pass through typical commercially available household toilets and plumbing drainage systems without causing clogging or similar problems that can be directly associated with the physical characteristics of the product. For the purpose of the appended claims, the products are evaluated for flushability via relative ease of toilet bowl and trap evacuation and subsequent transport through a simulated plumbing system. The flushability of such a device should be measured by the following test procedure.

The test procedure is designed to simulate two days of normal toilet usage for a family of 4 (2 men, 2 women). The test employs a flushing sequence to simulate the following conditions: male urination visits, female urination visits (including post urinary drying with tissue), disposal of the product (that is, the interlabial device or other device to be tested) with cleaning using tissue, and bowel movement visits. The amount of tissue to be used for each tissue flush is a normal loading of 2 strips of seven sheets. The normal loading is based on consumer research regarding typical habits and practices. The test is designed to simulate the conditions a product will encounter if it is flushed through a conventional toilet and into a municipal sewer or into a septic tank. Samples are evaluated for: 1) toilet bowl and trap clearance, 2) drain line blockage, and 3) disintegration during flushing.

Apparatus

An apparatus suitable for the flushability test is shown in plan view in FIG. 10. The apparatus includes:

- a 3.5 gallon (13.2 liter) water saver siphon vortex toilet referred to as 210 (additional toilets can also be attached to the piping layout shown in FIG. 17 to evaluate the behavior of test samples using different flushing mechanisms such as commercial, pressure toilets);
- approximately 59 feet (18 meters) of 4 inch (10 cm) inside diameter acrylic pipe (As can be seen from FIG. 17, the piping is assembled in roughly a square configuration having linear runs 211, 213, 215, 217, 219, 221 approximately 10 feet (3 meters) long);
- a cast iron tee 223 slightly downstream of the toilet 210 that is open to the atmosphere for venting;
- five cast iron ninety degree elbows 212, 214, 216, 218, and 220;
- a snag 222 positioned vertically (FIG. 18) approximately 15 feet from the pipe's terminal end and approximately 1 inch (2.5 cm) long; and
- a screen (No. 4 Tyler sieve) to capture solid effluent for evaluation of disintegration.

The apparatus used for this method is set up to be equivalent to ANSI Standard A112.19.2M-1990 for Vitreous China fixtures. The piping is plumbed to provide a drop of 0.25 inch per foot (2 centimeters/meter) of pipe length.

Materials

Tissue Product used in Test: standard "CHARMIN" toilet tissue manufactured by The Procter & Gamble Company of Cincinnati, Ohio.

Synthetic Fecal Material: Prepared according to the method described below

Test Flushing Sequence

The test flushing sequence simulates 2 days of normal toilet usage for a family of 4 (2 men, 2 women; based on consumer habits and practices research). The sequence of 34 total flushes consists of 14 flushes with an empty bowl, 8 flushes with tissue only, 6

flushes with tissue and the product to be tested and 6 flushes with tissue and simulated fecal matter (SFM). When it is used, the SFM is placed in the bowl just prior to the addition of tissue. The SFM loading of $160 \text{ g} \pm 5 \text{ g}$ consists of two 1 inch (2.5 centimeter) x 4 inch (10 centimeter) pieces and one 1 inch (2.5 centimeter) x 2 inch (5 centimeter) piece. 5
 10
 15
 20
 25
 30
 35
 40
 45
 50
 55
 60
 65
 70
 75
 80
 85
 90
 95
 100
 105
 110
 115
 120
 125
 130
 135
 140
 145
 150
 155
 160
 165
 170
 175
 180
 185
 190
 195
 200
 205
 210
 215
 220
 225
 230
 235
 240
 245
 250
 255
 260
 265
 270
 275
 280
 285
 290
 295
 300
 305
 310
 315
 320
 325
 330
 335
 340
 345
 350
 355
 360
 365
 370
 375
 380
 385
 390
 395
 400
 405
 410
 415
 420
 425
 430
 435
 440
 445
 450
 455
 460
 465
 470
 475
 480
 485
 490
 495
 500
 505
 510
 515
 520
 525
 530
 535
 540
 545
 550
 555
 560
 565
 570
 575
 580
 585
 590
 595
 600
 605
 610
 615
 620
 625
 630
 635
 640
 645
 650
 655
 660
 665
 670
 675
 680
 685
 690
 695
 700
 705
 710
 715
 720
 725
 730
 735
 740
 745
 750
 755
 760
 765
 770
 775
 780
 785
 790
 795
 800
 805
 810
 815
 820
 825
 830
 835
 840
 845
 850
 855
 860
 865
 870
 875
 880
 885
 890
 895
 900
 905
 910
 915
 920
 925
 930
 935
 940
 945
 950
 955
 960
 965
 970
 975
 980
 985
 990
 995
 1000
 1005
 1010
 1015
 1020
 1025
 1030
 1035
 1040
 1045
 1050
 1055
 1060
 1065
 1070
 1075
 1080
 1085
 1090
 1095
 1100
 1105
 1110
 1115
 1120
 1125
 1130
 1135
 1140
 1145
 1150
 1155
 1160
 1165
 1170
 1175
 1180
 1185
 1190
 1195
 1200
 1205
 1210
 1215
 1220
 1225
 1230
 1235
 1240
 1245
 1250
 1255
 1260
 1265
 1270
 1275
 1280
 1285
 1290
 1295
 1300
 1305
 1310
 1315
 1320
 1325
 1330
 1335
 1340
 1345
 1350
 1355
 1360
 1365
 1370
 1375
 1380
 1385
 1390
 1395
 1400
 1405
 1410
 1415
 1420
 1425
 1430
 1435
 1440
 1445
 1450
 1455
 1460
 1465
 1470
 1475
 1480
 1485
 1490
 1495
 1500
 1505
 1510
 1515
 1520
 1525
 1530
 1535
 1540
 1545
 1550
 1555
 1560
 1565
 1570
 1575
 1580
 1585
 1590
 1595
 1600
 1605
 1610
 1615
 1620
 1625
 1630
 1635
 1640
 1645
 1650
 1655
 1660
 1665
 1670
 1675
 1680
 1685
 1690
 1695
 1700
 1705
 1710
 1715
 1720
 1725
 1730
 1735
 1740
 1745
 1750
 1755
 1760
 1765
 1770
 1775
 1780
 1785
 1790
 1795
 1800
 1805
 1810
 1815
 1820
 1825
 1830
 1835
 1840
 1845
 1850
 1855
 1860
 1865
 1870
 1875
 1880
 1885
 1890
 1895
 1900
 1905
 1910
 1915
 1920
 1925
 1930
 1935
 1940
 1945
 1950
 1955
 1960
 1965
 1970
 1975
 1980
 1985
 1990
 1995
 2000
 2005
 2010
 2015
 2020
 2025
 2030
 2035
 2040
 2045
 2050
 2055
 2060
 2065
 2070
 2075
 2080
 2085
 2090
 2095
 2100
 2105
 2110
 2115
 2120
 2125
 2130
 2135
 2140
 2145
 2150
 2155
 2160
 2165
 2170
 2175
 2180
 2185
 2190
 2195
 2200
 2205
 2210
 2215
 2220
 2225
 2230
 2235
 2240
 2245
 2250
 2255
 2260
 2265
 2270
 2275
 2280
 2285
 2290
 2295
 2300
 2305
 2310
 2315
 2320
 2325
 2330
 2335
 2340
 2345
 2350
 2355
 2360
 2365
 2370
 2375
 2380
 2385
 2390
 2395
 2400
 2405
 2410
 2415
 2420
 2425
 2430
 2435
 2440
 2445
 2450
 2455
 2460
 2465
 2470
 2475
 2480
 2485
 2490
 2495
 2500
 2505
 2510
 2515
 2520
 2525
 2530
 2535
 2540
 2545
 2550
 2555
 2560
 2565
 2570
 2575
 2580
 2585
 2590
 2595
 2600
 2605
 2610
 2615
 2620
 2625
 2630
 2635
 2640
 2645
 2650
 2655
 2660
 2665
 2670
 2675
 2680
 2685
 2690
 2695
 2700
 2705
 2710
 2715
 2720
 2725
 2730
 2735
 2740
 2745
 2750
 2755
 2760
 2765
 2770
 2775
 2780
 2785
 2790
 2795
 2800
 2805
 2810
 2815
 2820
 2825
 2830
 2835
 2840
 2845
 2850
 2855
 2860
 2865
 2870
 2875
 2880
 2885
 2890
 2895
 2900
 2905
 2910
 2915
 2920
 2925
 2930
 2935
 2940
 2945
 2950
 2955
 2960
 2965
 2970
 2975
 2980
 2985
 2990
 2995
 3000
 3005
 3010
 3015
 3020
 3025
 3030
 3035
 3040
 3045
 3050
 3055
 3060
 3065
 3070
 3075
 3080
 3085
 3090
 3095
 3100
 3105
 3110
 3115
 3120
 3125
 3130
 3135
 3140
 3145
 3150
 3155
 3160
 3165
 3170
 3175
 3180
 3185
 3190
 3195
 3200
 3205
 3210
 3215
 3220
 3225
 3230
 3235
 3240
 3245
 3250
 3255
 3260
 3265
 3270
 3275
 3280
 3285
 3290
 3295
 3300
 3305
 3310
 3315
 3320
 3325
 3330
 3335
 3340
 3345
 3350
 3355
 3360
 3365
 3370
 3375
 3380
 3385
 3390
 3395
 3400
 3405
 3410
 3415
 3420
 3425
 3430
 3435
 3440
 3445
 3450
 3455
 3460
 3465
 3470
 3475
 3480
 3485
 3490
 3495
 3500
 3505
 3510
 3515
 3520
 3525
 3530
 3535
 3540
 3545
 3550
 3555
 3560
 3565
 3570
 3575
 3580
 3585
 3590
 3595
 3600
 3605
 3610
 3615
 3620
 3625
 3630
 3635
 3640
 3645
 3650
 3655
 3660
 3665
 3670
 3675
 3680
 3685
 3690
 3695
 3700
 3705
 3710
 3715
 3720
 3725
 3730
 3735
 3740
 3745
 3750
 3755
 3760
 3765
 3770
 3775
 3780
 3785
 3790
 3795
 3800
 3805
 3810
 3815
 3820
 3825
 3830
 3835
 3840
 3845
 3850
 3855
 3860
 3865
 3870
 3875
 3880
 3885
 3890
 3895
 3900
 3905
 3910
 3915
 3920
 3925
 3930
 3935
 3940
 3945
 3950
 3955
 3960
 3965
 3970
 3975
 3980
 3985
 3990
 3995
 4000
 4005
 4010
 4015
 4020
 4025
 4030
 4035
 4040
 4045
 4050
 4055
 4060
 4065
 4070
 4075
 4080
 4085
 4090
 4095
 4100
 4105
 4110
 4115
 4120
 4125
 4130
 4135
 4140
 4145
 4150
 4155
 4160
 4165
 4170
 4175
 4180
 4185
 4190
 4195
 4200
 4205
 4210
 4215
 4220
 4225
 4230
 4235
 4240
 4245
 4250
 4255
 4260
 4265
 4270
 4275
 4280
 4285
 4290
 4295
 4300
 4305
 4310
 4315
 4320
 4325
 4330
 4335
 4340
 4345
 4350
 4355
 4360
 4365
 4370
 4375
 4380
 4385
 4390
 4395
 4400
 4405
 4410
 4415
 4420
 4425
 4430
 4435
 4440
 4445
 4450
 4455
 4460
 4465
 4470
 4475
 4480
 4485
 4490
 4495
 4500
 4505
 4510
 4515
 4520
 4525
 4530
 4535
 4540
 4545
 4550
 4555
 4560
 4565
 4570
 4575
 4580
 4585
 4590
 4595
 4600
 4605
 4610
 4615
 4620
 4625
 4630
 4635
 4640
 4645
 4650
 4655
 4660
 4665
 4670
 4675
 4680
 4685
 4690
 4695
 4700
 4705
 4710
 4715
 4720
 4725
 4730
 4735
 4740
 4745
 4750
 4755
 4760
 4765
 4770
 4775
 4780
 4785
 4790
 4795
 4800
 4805
 4810
 4815
 4820
 4825
 4830
 4835
 4840
 4845
 4850
 4855
 4860
 4865
 4870
 4875
 4880
 4885
 4890
 4895
 4900
 4905
 4910
 4915
 4920
 4925
 4930
 4935
 4940
 4945
 4950
 4955
 4960
 4965
 4970
 4975
 4980
 4985
 4990
 4995
 5000
 5005
 5010
 5015
 5020
 5025
 5030
 5035
 5040
 5045
 5050
 5055
 5060
 5065
 5070
 5075
 5080
 5085
 5090
 5095
 5100
 5105
 5110
 5115
 5120
 5125
 5130
 5135
 5140
 5145
 5150
 5155
 5160
 5165
 5170
 5175
 5180
 5185
 5190
 5195
 5200
 5205
 5210
 5215
 5220
 5225
 5230
 5235
 5240
 5245
 5250
 5255
 5260
 5265
 5270
 5275
 5280
 5285
 5290
 5295
 5300
 5305
 5310
 5315
 5320
 5325
 5330
 5335
 5340
 5345
 5350
 5355
 5360
 5365
 5370
 5375
 5380
 5385
 5390
 5395
 5400
 5405
 5410
 5415
 5420
 5425
 5430
 5435
 5440
 5445
 5450
 5455
 5460
 5465
 5470
 5475
 5480
 5485
 5490
 5495
 5500
 5505
 5510
 5515
 5520
 5525
 5530
 5535
 5540
 5545
 5550
 5555
 5560
 5565
 5570
 5575
 5580
 5585
 5590
 5595
 5600
 5605
 5610
 5615
 5620
 5625
 5630
 5635
 5640
 5645
 5650
 5655
 5660
 5665
 5670
 5675
 5680
 5685
 5690
 5695
 5700
 5705
 5710
 5715
 5720
 5725
 5730
 5735
 5740
 5745
 5750
 5755
 5760
 5765
 5770
 5775
 5780
 5785
 5790
 5795
 5800
 5805
 5810
 5815
 5820
 5825
 5830
 5835
 5840
 5845
 5850
 5855
 5860
 5865
 5870
 5875
 5880
 5885
 5890
 5895
 5900
 5905
 5910
 5915
 5920
 5925
 5930
 5935
 5940
 5945
 5950
 5955
 5960
 5965
 5970
 5975
 5980
 5985
 5990
 5995
 6000
 6005
 6010
 6015
 6020
 6025
 6030
 6035
 6040
 6045
 6050
 6055
 6060
 6065
 6070
 6075
 6080
 6085
 6090
 6095
 6100
 6105
 6110
 6115
 6120
 6125
 6130
 6135
 6140
 6145
 6150
 6155
 6160
 6165
 6170
 6175
 6180
 6185
 6190
 6195
 6200
 6205
 6210
 6215
 6220
 6225
 6230
 6235
 6240
 6245
 6250
 6255
 6260
 6265
 6270
 6275
 6280
 6285
 6290
 6295
 6300
 6305
 6310
 6315
 6320
 6325
 6330
 6335
 6340
 6345
 6350
 6355
 6360
 6365
 6370
 6375
 6380
 6385
 6390
 6395
 6400
 6405
 6410
 6415
 6420
 6425
 6430
 6435
 6440
 6445
 6450
 6455
 6460
 6465
 6470
 6475
 6480
 6485
 6490
 6495
 6500
 6505
 6510
 6515
 6520
 6525
 6530
 6535
 6540
 6545
 6550
 6555
 6560
 6565
 6570
 6575
 6580
 6585
 6590
 6595
 6600
 6605
 6610
 6615
 6620
 6625
 6630
 6635
 6640
 6645
 6650
 6655
 6660
 6665
 6670
 6675
 6680
 6685
 6690
 6695
 6700
 6705
 6710
 6715
 6720
 6725
 6730
 6735
 6740
 6745
 6750
 6755
 6760
 6765
 6770
 6775
 6780
 6785
 6790
 6795
 6800
 6805
 6810
 6815
 6820
 6825
 6830
 6835
 6840
 6845
 6850
 6855
 6860
 6865
 6870
 6875
 6880
 6885
 6890
 6895
 6900

- 3) Flush With Tissue Only - Take a drain line blockage reading 2 minutes after the water reaches the snag point, wait 1 additional minute, and move to step 4.
- 4) Flush With Empty Bowl. Take a drain line blockage reading 2 minutes after the water reaches the snag point.

Total number of flushes per sequence is 34.

If, after the second flush in the flushing sequence, the product remains in the bowl or trap after flushing, the tissue and or product is plunged into the drainage line manually and the flushing sequence will continue. After completion of each trial loading, the drainage pipe will be cleared prior to beginning subsequent testing.

The above described flushing sequence is repeated three times for each test product.

Data Reporting

The degree of drain line blockage is determined by measuring the length of water dammed up behind the obstruction. Graduations are marked every 12 inches (30 centimeters) on the drainpipe upstream of the obstruction. Each one foot length that the water is backed up corresponds to 0.25 inch (0.6 centimeter) or 6.25% of blockage at the obstruction point. Test product residues which exit the drainpipe are also collected.

The following data are recorded for each evaluation:

- 1) Incidence of failure (%) of the product to clear bowl and trap in one flush
- 2) Incidence of failure (%) of the product to clear bowl and trap in two flushes
- 3) Incidence of product on simulated snag
- 4) Maximum level (%) of drain line blockage
- 5) Cumulative level (%) of drain line blockage over the 2 day simulated test period.

Preferably, the products described herein will completely clear the bowl at least about 70% of the time in two or fewer flushes, more preferably at least about 80% of the time in one flush, even more preferably at least about 90% of the time in one flush, and

most preferably at least about 95% of the time in one flush. The products described herein will preferably have a maximum level of drain line blockage of less than or equal to about 80%. The products described herein will preferably have a cumulative level of drain line blockage over the 2 day simulated test period of less than or equal to about 50%.

Preparation of Synthetic Fecal Material

I. Materials Needed:

- Feclone synthetic fecal matter (900 grams);
(Available from Siliclone Studio, Valley Forge, PA as product BFPS-7 dry concentrate)
- Tap water at 100° C (6066 grams)

II. Equipment Needed:

- Mixer (Available from Hobart Corp., Troy, OH as Model A200)
- Extruder (Available from Hobart Corp., Troy, OH as Model 4812)
- Disposable Centrifuge tubes with screw caps (50 ml) (Available from VWR Scientific, Chicago, IL as Catalog No. 21-008-176)
- Water Bath to control temperature to 37° C.

III. Preparation:

1. Pour the 100° C water into the mixing bowl of the mixer and add the dry Feclone concentrate.
2. Mix on low for 1 minute.
3. Mix on medium speed for 2 minutes.
4. After the material is well mixed, transfer to the extruder.
5. Using an ice pick, punch a small hole in the tip of each centrifuge tube.
6. Extrude the Feclone into the centrifuge tubes.

7. Cap the centrifuge tubes and store in the refrigerator.
8. Before using, put the tubes in the water bath at 38° C.

28 Day Sludge Test

Purpose:

- 5 To determine the extent to which an absorbent article disintegrates upon exposure to biologically active anaerobic sludge. Anaerobic conditions are typically found in household septic tanks, as well as in municipal sewage treatment facilities in the form of anaerobic sludge digesters. Test products, such as the absorbent article are combined with anaerobic digester sludge to determine the extent and rate of disintegration of test
- 10 products over a 28 day period. Disintegration (as measured by weight change) is typically measured on days 3, 7 14, 21 and 28 of the particular study. This protocol is modeled after the National Sanitation Foundation, Ann Arbor, Michigan, International Protocol: Evaluation of the Anaerobic Disintegration of a Test Product, November, 1992.

Materials:

- 15 Control Product

TAMPAX Regular brand tampons will be used as a positive control product in the anaerobic disintegration test.

Material Preparation

- 20 Prior to the addition of the test and control products to the reactors, the materials will be dried in a hot air oven at $103^{\circ} \pm 2^{\circ}\text{C}$ for 2 hours and then weighed to determine the initial weight. Approximately equal weights of the control and the test products will be placed in respective reactors.

Anaerobic sludge:

- 25 The sludge used in this evaluation will be anaerobic sludge obtained from a municipal waste water treatment plant, or raw sewage obtained as influent from a waste water treatment plant that has been concentrated by settling and decanting the overlying water. Prior to use in the evaluation, the following parameters of the sludge will be measured in accordance with standard laboratory operating procedures:

Total solids

Total volatile solids

pH

The sludge should meet the following criteria for use in the evaluation:

5 pH between 6.5 and 8

Total solids $\geq 15,000$ mg/L

Total volatile solids $\geq 10,000$ mg/L

The criteria for the activity of the sludge requires that the control tampon material must lose at least 95% of its initial dry weight after 28 days exposure.

10 Procedure:

The test and control products are added to a 2L wide mouth glass flask (reactor) containing 1500 ml of anaerobic digester sludge or concentrated raw sewage. Three reactor flasks per test material per sampling day are prepared. Thus, if disintegration is measured on days 3, 7, 14, 21, and 28, there will be a total of 15 reactor flasks for the test product and 15 flasks for the control product. The reactors are sealed and placed in an incubator maintained at $35 \pm 2^\circ\text{C}$. On the specified sampling days, three reactors each for the test and control material are removed from the incubator. On the designated sample days, the contents of each reactor will be passed through a 1mm mesh screen to recover any undisintegrated material. Any collected material will be rinsed with tap water, removed from the screen and placed in a hot air oven at $103 \pm 2^\circ\text{C}$ for at least 2 hours. The dried material will be weighed to determine final weight. Visual observations of the physical appearance of the materials when recovered from the reactors will also be made and recorded.

Results:

25 The rate and extent of anaerobic disintegration of each test material and the control material is determined from initial dry weights of the material and the dried weights of the material recovered on the sampling days. The percent anaerobic disintegration is determined using the following equation (percent weight loss):

$$\text{Percent Disintegration} = \frac{(\text{initial dry weight} - \text{final dry weight})}{(\text{initial dry weight})} \times 100$$

The average percent disintegration for the test and control products for each sampling day will be presented. For the purposes of the appended claims, the percent
 5 disintegration values are for day 28 of the study.

The disclosure of all patents, patent applications (and any patents which issue thereon, as well as any corresponding published foreign patent applications), and publications mentioned throughout this description are hereby incorporated by reference herein. It is expressly not admitted, however, that any of the documents incorporated by
 10 reference herein teach or disclose the present invention.

While particular embodiments of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention.

Finished Product V-Bend Test

15 A. *Vertical Bend*

The finished product V-bend test method assesses the longitudinal stiffness of a product that is designed to be inserted into the interlabial vestibule of a female for the purposes of absorbing and containing bodily discharges. A key aspect of delivering
 20 superior fluid containment and soiling performance is the correct placement of the interlabial product within the labial vestibule and specifically at a depth sufficiently close to the vaginal opening to avoid by-pass soiling. This test measures the resistance of the product to bend and thereby adapt to the particular labial structure during the products insertion and application to the labial vestibule. The greater the products' resistance
 25 (stiffness) to bend and deform during application the less likely is the product can be inserted; applied to the depth required to deliver optimal management of the discharged

bodily fluids; and avoid by-passing the absorbent structure. This method is an approach to determining the “beam stiffness” of an interlabial product along its centerline.

Objective:

- Determine the resistance of an interlabial product to deform along its longitudinal centerline during the application process. Assess the ability of the interlabial product to conform to the wearers anatomical shape (longitudinal centerline) during product application and insertion.

Instrument Setup:

1. Crosshead speed = 500 mm/min
2. Crosshead travel = 25mm in compression
3. Data rate = 400 Hz
4. Upper assembly consists of light duty grips using 1 inch by 1 inch rubber coated faces.
5. Lower 3 point bend assembly uses (2) 5mm (diameter) stainless roller supports (MTS model number 642.01A).
6. Lower assembly is set to a 75mm span.
7. Gauge length—measures from the plane created by the *top* of the two stainless rollers and the *bottom* of the upper grip faces—is set at 15mm.
8. The room climatic conditions should be controlled to TAPPI standards (25%C, 50% humidity).

Execution:

1. As shown in Figure 24, the test sample pad 300 is placed into the light dum pneumatic grips 301, centers between the lower 3-point bend assembly (MTS 642.014) 302.
2. As shown in Figure 25, lower edge of test sample pad 300 is aligned with the lower edge of the lower 3-point bend assembly (MTS 642.014) 302 rubber-faced grips, before activating light dum pneumatic grips 301 (the product may bulge slightly once the grips are activated).

Reporting:

1. **Peak Load:** The peak load that occurs while bending the pad across the 75 mm span. It is important that the Peak Load is calculated before any pad compression occurs.
2. **“Bending Stiffness”:** This is a measure of the slope of the initial linear portion of the stress strain curve—reported in kPa. It’s formula is:

$$\text{“Bending Stiffness”} = (\text{Slope} * \text{Gauge Length}) / \text{Area}$$

Where

- **Slope** = peak slope that occurs between any two points that encompass 50% of the stress-strain curve.
- **Gauge Length** = 15mm
- **Area** = 645.16 sq mm (1 sq inch)

- Gauge Length and Area generally apply to tensile tests, but for our purposes, using these values allow us to keep comparisons between samples the same. What we are after is a of the slope of the initial, linear portion of each stress-strain curve. We could, more directly, use the Slope only, but historically, we have calculated a modulus-like quantity, holding gauge length and cross-sectional area constant.

B. “Free” Vertical Bend

Free VBEND uses the same protocol as VBEND, noting the following exceptions:

1. As shown in Figures 26 and 27, test sample pad 301 is held by keel and sides of pad 301 are free.

General Test Execution:

I. Products featuring an external insertion device (attached keel or insertion aid implement)

1. Remove the interlabial product carefully from any protective packaging and without bending or otherwise deforming the product carefully placed on the test surface.
2. Equilibrate the products for a period of 30 minutes prior to performing any measurements.
3. Measure and record the physical characteristics of the product such as lengths, widths, thickness.
4. Select a fresh undisturbed sample and secure the product within the set-up clamps jaws as would normally be done by a product user grasping the product prior to

insertion/application. Carefully place and center the product above the test apparatus.

In this case the product is expected to be secured by an external handle/grip/keel or other attachment means including a disposable or reusable insertion device. If no external attachment grip or device is present then go to step 8 below.

- 5 5. The test is commenced and the force as a function of crosshead position (as the cross traverses its programmed distance) is recorded by the data logging software.
6. The peak force (resistance in g) to deform the product is determined as is the slope of the force versus distance traveled line (modulus in Kpa).
7. Repeat the test on multiple samples to ensure a reliable estimate of the products resistance to deform during application.

II. Products not featuring an external grasping means or an insertion aid

1. Measure and record the physical characteristics of the product such as lengths, widths, thickness.
- 15 2. Select a fresh undisturbed sample and secure the product within the set-up clamps jaws as would normally be done by a product user grasping the product prior to insertion/application. Carefully place and center the product above the test apparatus. In this case the product is expected to be secured by grasping the absorbent body rather than an external attachment means.
- 20 3. The test is commenced and the force as a function of crosshead position (as the cross traverses its programmed distance) is recorded by the data logging software.

4. The peak force (resistance in g) to deform the product is determined as is the slope of the force versus distance traveled line (modulus in Kpa).
5. Repeat the test on multiple samples to ensure a reliable estimate of the products resistance to deform during application.

5

Test Results and Conclusions:

The peak force which is measured corresponds to the resistance of the product to deform during a simulated insertion / application process. The lower the peak force (in grams) that is measured the less resistance a woman will encounter during the application process and the more likely the product user is likely to achieve a deep and successful product insertion / application. For a product featuring an external insertion device (attached keel or insertion aid implement), ideally, the peak force is less than 40 g and more preferred is less than 30 g and most preferred less than 20g. For a product not featuring an external insertion device (attached keel or insertion aid implement), ideally, the peak force is less than 50 g and more preferred is less than 40 g and most preferred less than 30g. These numbers are directionally higher due to the fact that the absorbent core structure is typically grasped and this clamping imparts a degree of resistance to the structure during the test.

Finished Product L-Bend

The finished product L-bend test method assesses the overall stiffness of product is inserted into the interlabial vestibule of a female for the purposes of absorbing and containing bodily discharges. A key aspect of delivering superior fluid containment,

soiling performance and overall product comfort is the correct placement of the interlabial product within the labial vestibule; the ability of the product to conform to the labial surface contours (structure/shape); and the ability of the product to adapt its shape according to changes in the labial vestibule shape that accompanies bodily motions. This

5 test measures the resistance of the product to deform / bend along its lateral (cross direction) centerline, as would be found while wearing the product in use. This is particularly important if the interlabial product longitudinal length exceeds the longitudinal length of the labial vestibule as measured between the anterior and posterior commissure. The greater the products' resistance (stiffness) to bend and deform while

10 being worn the less comfortable the product will be perceived as being. Further the less a product is able to bend / deform around this center line the higher is the likelihood of soiling since the product is less likely to conform to the labial shape and bodily discharges have the opportunity to by-pass the product during bodily motion.

Objective:

15 Determine the resistance of an interlabial product to deform along its cross direction centerline during the application process. Assess the potential of the interlabial product to conform to changes in anatomical shape (within the labial vestibule) during bodily motion.

Instrument Setup:

20 As shown in Figures 28 and 29, The LBEND method uses the same instrument setup as the VBEND except the following exceptions:

1. In place of pneumatic grips, LBEND uses a third 5mm stainless roller 305 (creating a true three point bend test). The upper stainless roller 305 must be centered and parallel to the lower assembly span.
2. Gauge length of 15mm is measured from the *bottom* of the upper roller to the plane created by the *tops* of the lower rollers.
3. The lower assembly span 302 is set to 25mm.
4. The test sample pad 305 is placed on its side on the lower assembly, with its' keel centered on the 25mm span. If the keel is significantly off-center in the product, the test sample pad 305 should be discarded.
5. Excessively thick pads should not be tested with this method—this method is intended to measure beam stiffness, not force required to compress the sample. Since the lower span is only 25mm, very thick pads will produce high forces, not from stiffness, but from the force required to “stuff” the pad into the 25mm gap.

Test Execution:

1. Remove the interlabial product carefully from any protective packaging and without bending or otherwise deforming the product carefully placed on the test surface.
2. Equilibrate the products for a period of 30 minutes prior to performing any measurements.
3. Measure and record the physical characteristics of the product such as lengths, widths, thickness.

4. Select a fresh undisturbed sample and the carefully place the product centrally, on its side onto the supporting jaw and below (15mm) the displacement rod.
5. The test is commenced and the force as a function of crosshead position (as the cross traverses its programmed distance) is recorded by the data logging software. This
- 5 force corresponds to the force required to deform the product transversely along its centerline.
6. The peak force (resistance in g) to deform the product is determined as is the slope of the force versus distance traveled line (modulus in Kpa).
7. Repeat the test on multiple samples to ensure a reliable estimate of the products'
- 10 resistance to deform during application.

Test Results and Conclusions:

- The "peak force" measured corresponds to the resistance of the product to bend / deform and conform during a simulated bending motion. The lower the peak force (in grams) measured the less resistance a woman will encounter during bodily motion leading to an
- 15 improved wearing comfort experience. Ideally, the peak force should be less than 200 g and more preferred is less than 140 g and most preferred less than 90g. In addition to the peak force the product may require to bend / distort and conform during bodily motion the product may also distort the surrounding tissues as the product bends/distorts or conforms as a result of bodily motion. The lower the stiffness to bending of the product the less the
- 20 surrounding tissues are distorted and the lower the pressure the product exerts on these tissues. Ideally, the product has a "bending stiffness" less than 5 kPa, more preferably less than 3 kPa, most preferably less than 2 kPa.

Finished Product Keel Insertion Stiffness Test

The finished product keel insertion stiffness test method assesses the overall stiffness of product that has been inserted into the interlabial vestibule of a female for the purposes of absorbing and containing bodily discharges. A key aspect of delivering superior fluid containment and soiling performance is the correct placement depth of the interlabial product within the labial. Ideally the product is placed to a depth sufficient to capture bodily discharges as they exit the body (introits or urethra). This facilitates through a product that readily bends and offers minimal resistance during product application / insertion (see V-bend method above) and preferably combined with a controlling member such as a grip/handle/keel or insertion aid. Externally (or internally) applying controlling members are generally stiffer than other product elements to facilitate insertion / application control. By restricting their dimensions (length, width, height) it is possible to achieve insertion control without imparting discomfort to the product wearer from the stiffer controlling member. This test measures the stiffness of an externally (or internally) applied insertion controlling member that is designed to remain affixed to the product during the entire wearing period after product insertion / application. Removable or disposable application aids are not assessed in this test as they are required to meet product comfort requirements only during the insertion / application phase and not during the wearing phase.

Objective:

Determine the stiffness of an affixed insertion / application controlling member.

Assess the potential of the controlling member to facilitate application or induce discomfort.

5 Instrument Setup:

As shown in Figures 30 and 31, keel stiffness method uses the same instrument setup as the VBEND except the following exceptions:

1. The pneumatic grips (1in X 1 in, rubber faced) 306 hold approximately 5mm of the keel of the test sample 307.
- 10 2. The gauge length is adjusted for each sample, allowing the bottom of the sample 307 (held by keel) to just hover (<1mm) above a horizontal platen 308. *For the purposes of calculation, the software should still continue to use a 15mm gauge length.*
3. The crosshead is set to travel at 100mm/min to a 7mm extension point.
- 15 4. Careful attention should be paid to make sure that the pad 307 itself is not being compressed between the grips 306 and platen 308 —only the keel is to be compressed.

Test Execution:

1. Remove the interlabial product carefully from any protective packaging and without
20 bending or otherwise deforming the product carefully placed on the test surface.

2. Equilibrate the product for a period of 30 minutes prior to performing any measurements.
3. Measure and record the physical characteristics of the product such as lengths, widths, thickness.
- 5 4. Select a fresh undisturbed sample and the carefully place the product on its upper surface so as to expose its attached keel or controlling member.
5. Position the keel or attached member within the jaw of the test equipment so as to be centrally positioned and such that about 5mm of the attached member is held within the equipment jaw.
- 10 6. Suspend the product so that it is position ed (see Figures 30 and 31) just above the equipments lower measurement plate.
7. Commence the test and the force as a function of crosshead position (as the cross traverses its programmed distance and compresses the product via the keel) is recorded by the data logging software.
- 15 8. The peak force (resistance in g) to deform the product is determined as is the slope of the force versus distance traveled line (modulus in Kpa). This force corresponds to the force required to deform the product and keel or controlling member during a compression (i.e. sitting) or the resistive force that would be required to deform the keel structure during product insertion / application.

9. Repeat the test repeated on multiple samples to ensure a reliable estimate of the products resistance to deform during application.

Test Results and Conclusions:

- The “keel stiffness” is a measure of the resistance of the keel structure (at product attachment point) to bend or deform either during the insertion / application process or in a compression situation (such as sitting down) while the product is at work. Ideally, for the insertion phase of product application a higher “keel stiffness” is preferred to ensure the maximum control and reproducibility of product placement within the labial vestibule. However the presence of an overly stiff keel or controlling member on the product while it is actually being worn can result in an uncomfortable poking during some body positions such as sitting and leg crossing. Typically the keel or controlling member will protrude beyond the folded product height in use. During sitting the tissues within the labia are compressed. A too stiff keel or controlling member will resist the compression and transmit this compressive force unduly onto the labial tissues and surface and potentially jam the product up against the labial vestibule floor. In the keel stiffness test method a keel (or controlling member) stiffness is preferably greater than 10g and less than 60 g and more preferred greater than 20g and less than 40 g and most preferred between 30g and 40g. In addition to the peak force how the product deforms during bodily motion is also important.
- 20 If a detachable or disposable insertion aid is utilized a stiffness in excess of 20 g, preferably more than 30 g and most preferably more than 40 g in this test design is chosen to ensure adequate control of the product during the insertion / application phase.